IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

ARBUTUS BIOPHARMA CORPORATION and GENEVANT SCIENCES GMBH

Plaintiffs,

v.

MODERNA, INC. and MODERNATX, INC.,

Defendants.

MODERNA, INC. and MODERNATX, INC.,

Counterclaim-Plaintiffs,

v.

ARBUTUS BIOPHARMA CORPORATION and GENEVANT SCIENCES GMBH,

Counterclaim- Defendants.

Redacted - Public Version

C.A. No. 22-252-JDW

JURY TRIAL DEMANDED

DECLARATION OF MATTHEW W. LACHMAN, ESQ.

- I, Matthew W. Lachman, declare under penalty of perjury that the following is true and correct:
- 1. I am an attorney practicing with the firm of Williams & Connolly LLP, representing Plaintiff Genevant Sciences GmbH ("Genevant"), in this action. I am familiar with the authenticity of the documents attached and I submit this declaration in support of Plaintiffs' Opening Summary Judgment Brief, Opening Brief in Support of Motion to Exclude Certain Expert Testimony of Drs. Anderson and Prud'homme, and Plaintiffs' Statements of Uncontested

Facts in Support of Motion for Summary Judgment. The Exhibits listed below are cited in the Briefs and Statements of Uncontested Facts.

2. Attached as Exhibits 1 through 29 to this declaration are true copies of the following documents:

Number	Description	ECF Title		
1 Moderna's Identification of § 102/103 and § 112 Inva		Moderna Invalidity		
	Defenses Pursuant to D.I. 475, dated June 9, 2025	Disclosures		
2	Letter from M. McLennan to S. Mahaffy (Sept. 19, 2023)	Sept. 19, 2023		
	("Sept. 19, 2023 Letter")	Letter		
3	Excerpt from Moderna's Final Invalidity Contentions, dated	Moderna's Final		
	June 28, 2024	Invalidity		
		Contentions		
4	Excerpt from Opening Expert Report of Dr. Daniel Griffith	Anderson Opening		
	Anderson	Report		
5	Excerpt from Responsive Expert Report of Dr. Niren	Murthy Validity		
	Murthy Regarding Validity*	Report		
6	Excerpt from Reply Expert Report of Dr. Daniel Griffith	Anderson Reply		
	Anderson*	Report		
7	Excerpt from Opening Expert Report of Dr. Robert	Prud'homme		
	Prud'homme, PhD	Opening Report		
8	Excerpt from Expert Report of Dr. Pierre Meulien, Ph.D.	Meulien Opening		
		Report		
9	Excerpt from Reply Invalidity Expert Report of Dr. Robert	Prud'homme Reply		
	Prud'homme, PhD*	Report		
10	Excerpt from Deposition Transcript of Dr. Robert	Prud'homme Dep.		
	Prud'homme, PhD, dated Apr. 16, 2025	Tr.		
11	Excerpt from Reply Report of Dr. Pierre Meulien, Ph.D.	Meulien Reply		
1.0		Report		
12	Excerpt from Dr. Lorne Palmer Laboratory Notebook 0608,	Dr. Palmer		
	dated Nov. 29, 2013 (GENV-00070361)	11/29/2013 Lab		
1.2	F	Notebook		
13	Excerpt from Mr. Stephen Reid Laboratory Notebook 0123,	Mr. Reid 2/12/2009		
1.4	dated Feb. 12, 2009 (GENV-00523502)*	Lab Notebook		
14	Excerpt from Deposition Transcript of Mr. Stephen Reid,	Reid Dep. Tr.		
1.5	dated May 28, 2024*	C 11 2012		
15	Andrew J. Geall et al., Nonviral delivery of self-amplifying	Geall 2012		
	RNA vaccines, 109 (36) PROC. NATL. ACAD. SCI. U.S.A.			
	14604-14609 (2012) ("Geall 2012")			

-

^{*} Pursuant to confidentiality agreements, the names of certain third-party entities have been redacted from this exhibit. These names are not relevant to Plaintiffs' motions, but Plaintiffs can file unredacted copies at the Court's request.

16	Sedic et al., Safety Evaluation of Lipid Nanoparticle-	Sedic 2018		
	Formulated Modified mRNA in the Sprague-Dawley Rat			
	and Cynomolgus Monkey, 55 VETERINARY PATHOLOGY 341			
1.5	(2018) ("Sedic 2018")	x 2022		
17	Jerry Leung et al., Genetically engineered transfusable	Leung 2023		
	platelets using mRNA lipid nanoparticles, 9(48) SCIENCE			
	ADVANCES 1–13 (2023) ("Leung 2023") and excerpt from			
1.0	supplemental figures	W/O 2012/000640		
18	Excerpt from de Fougerolles et al. WO 2013/090648 ("WO	WO 2013/090648		
1.0	2013/090648")	G1 1 2002		
19	Erika Check, RNA to the rescue?, 425 NATURE 10–12	Check 2003		
	(2003) ("Check 2003")) (1 1 1 0 · ·		
20	Excerpt from Opening Expert Report of Dr. Michael	Mitchell Opening		
	Mitchell	Report		
21	Non-Exclusive License Agreement by and between Acuitas	December 2016		
	Therapeutics Inc. and ModernaTX, Inc., dated Dec. 14,	Acuitas Sublicense		
	2016			
22	Non-Exclusive License Agreement by and between Acuitas	May 2015 Acuitas		
	Therapeutics Inc. and ModernaTX, Inc., dated May 22,	Sublicense		
	2015	2016		
23	Non-Exclusive License Agreement by and between Acuitas	October 2016		
	Therapeutics Inc. and ModernaTX, Inc., dated Oct. 12, 2016	Acuitas Sublicense		
24	Non-Exclusive License Agreement by and between Acuitas	August 2016		
	Therapeutics Inc. and ModernaTX, Inc., dated Aug. 19,	Acuitas Sublicense		
	2016			
25	Excerpt from Deposition Transcript of Dr. Sunny Himansu,	Himansu Dep. Tr.		
	dated Nov. 17, 2023			
26	Excerpt of Arbutus Form 8-K, dated Feb. 22, 2018	Arbutus 2018 8-K		
27	Excerpt of bioRxiv Preprint of Corbett et al., SARS-CoV-2	Corbett 2020		
	mRNA vaccine design enabled by prototype pathogen	Preprint		
	preparedness, 586 NATURE 567 (2020), dated June 11, 2020			
28	Excerpt of Corbett et al., SARS-CoV-2 mRNA vaccine	Corbett 2020		
	design enabled by prototype pathogen preparedness, 586			
	NATURE 567 (2020) ("Corbett 2020")			
29	Excerpt from IPR2018-00739 U.S. Patent No. 9,364,435	Moderna 435 IPR		
	Paper 28, Petitioner's Reply to Patent Owner Response	Reply		
	("Pet'r Reply")			

3. I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on: July 25, 2025

/s *Matthew W. Lachman*Matthew W. Lachman

CERTIFICATE OF SERVICE

I hereby certify that on July 25, 2025, this document was served on the persons listed

below in the manner indicated:

BY EMAIL:

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/s/ Matthew W. Lachman
Matthew W. Lachman

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EXHIBIT 23

Non-Exclusive License Agreement

by and between

Acuitas Therapeutics Inc.

and

ModernaTX, Inc.

October 12, 2016

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List of Appendices

Appendix A	License	i Target

Appendix B Applicable In-Licenses

Appendix C Certain Patents within the Licensed Technology

as of the License Agreement Effective Date

Schedule 9.2 Exceptions to Acuitas' Representations and Warranties

Non-Exclusive License Agreement

This Non-Exclusive License Agreement (this "License Agreement"), dated as of October 12, 2016 (the "License Agreement Effective Date"), is made by and between Acuitas Therapeutics Inc., a British Columbia corporation ("Acuitas"), and ModernaTX, Inc. (formerly known as Moderna Therapeutics, Inc.), a Delaware Corporation ("Moderna"). Each of Acuitas and Moderna may be referred to herein as a "Party" or together as the "Parties."

WHEREAS, Acuitas has proprietary LNP Technology;

WHEREAS, Moderna has proprietary messenger RNA ("mRNA") technologies; and

WHEREAS, Acuitas and Moderna are parties to that certain Development and Option Agreement (dated July 3, 2014) (the "<u>Development and Option Agreement</u>") pursuant to which Moderna has an option to take a license under Licensed Technology (as defined below) with respect to certain mRNA products;

WHEREAS, pursuant to the terms of the Development and Option Agreement, Moderna has exercised an option with respect to a Reserved Target and the Parties are now entering into a non-exclusive licensing arrangement whereby Moderna will have a non-exclusive license under the Licensed Technology to develop and commercialize Licensed Products, all on the terms and conditions set forth here.

NOW, THEREFORE, in consideration of the mutual covenants contained herein, and for other good and valuable consideration, the amount and sufficiency of which are hereby acknowledged, the Parties hereby agree as follows:

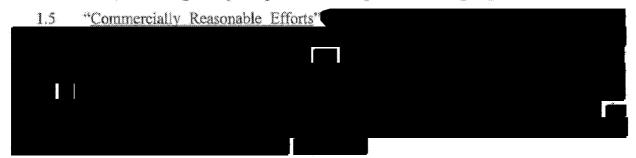
1. Definitions.

The following terms and their correlatives will have the meanings set forth below. Capitalized terms used, but not defined, herein will have the meanings ascribed to such terms in the Development and Option Agreement.



- 1.2 "Applicable In-Licenses" means all LNP In-Licenses that Moderna has elected to list on Appendix B as of the License Agreement Effective Date, plus any other LNP In-Licenses that Moderna has elects to include as an Applicable In-License pursuant to Section 4.1.
- 1.3 "Combination Product" means a Licensed Product that includes at least one additional active ingredient other than an mRNA Construct. Drug delivery vehicles, adjuvants, and excipients shall not be deemed to be "active ingredients", except in the case where such delivery vehicle, adjuvant, or excipient is recognized as an active ingredient in accordance with 21 C.F.R. 210.3(b)(7), provided however,
- 1.4 "Commercialization" means any and all activities directed to the Manufacturing, marketing, detailing, promotion and securing of reimbursement of a product after Regulatory Approval has been obtained (including making, having made, using, importing, selling and

offering for sale such product), and will include post-approval clinical studies, post-launch marketing, promoting, detailing, marketing research, distributing, customer service, administering and commercially selling such product, importing, exporting or transporting such product for commercial sale, and all regulatory compliance with respect to the foregoing.



- 1.6 "Contract Year" means the period beginning on the License Agreement Effective Date and ending on the first anniversary of the License Agreement Effective Date, and each consecutive twelve (12) month period thereafter during the Term.
- 1.7 "Control" or "Controlled" means, with respect to any Know-How or Patent, the possession (whether by ownership or license, other than by a license or sublicense granted pursuant to this License Agreement) by a Party or its Affiliates of the ability to grant to the other Party a license or access as provided herein to such item, without violating the terms of any agreement or other arrangement with any Third Party.
- 1.8 "Covers", with reference to (a) a Patent, means that the making, using, selling, offering for sale or importing of a product or practice of a method would infringe a Valid Claim or Pending Claim of such Patent in the country in which such activity occurs, and (b) Know-How, means that the Manufacture, Development or Commercialization of a product incorporates or embodies such Know-How.
- 1.9 "Cross License Agreement" means the Cross License Agreement dated November 12, 2012 by and between Acuitas and Tekmira Pharmaceuticals Corporation (on behalf of itself and its wholly owned Affiliate Protiva Biotherapeutics Inc.) ("Tekmira").
- 1.10 "Development" means preclinical and clinical drug research and development activities, including: test method development and stability testing, toxicology, formulation, process development, qualification and validation, Manufacture scale-up, development-stage Manufacturing, quality assurance/quality control, clinical studies, statistical analysis and report writing, the preparation and submission of applications for Regulatory Approval, regulatory affairs with respect to the foregoing and all other activities necessary or useful or otherwise requested or required by a Regulatory Authority as a condition or in support of obtaining or maintaining a Regulatory Approval.
 - 1.11 "Field of Use" means all fields.
- 1.12 "<u>First Commercial Sale</u>" means the first sale for use or consumption of any Licensed Product in a country after all required Regulatory Approvals for commercial sale of such Licensed Product have been obtained in such country.
- 1.13 "Generic Product" means, with respect to a Licensed Product in a given country, any generic or biosimilar product sold by a Third Party not licensed or otherwise authorized by or on

behalf of Moderna or any of its Affiliates or Sublicensees (a) that is approved for administration to humans under 351(k) of the PHSA referencing Licensee's Regulatory Filings; or (b) foreign equivalents that have received equivalent Regulatory Approval from the applicable Regulatory Authority by referencing Acuitas' Regulatory Filings (and data therein) of such Licensed Product. Notwithstanding anything to the contrary set forth above, in no event will a product sold by or under authority of Tekmira pursuant to the Cross License Agreement be a "Generic Product" for the purposes of this.

- 1.14 "In-License Payments" means any amounts paid or payable by Acuitas or its Affiliates under any Applicable In-License that arise solely as a result of the grant of a sublicense thereunder to Moderna and its Affiliates and Sublicensees that are royalties on sales of Licensed Products or milestone payments achieved with respect to License Products. For the avoidance of doubt, "In-License Payments" shall include only royalties and milestone payments payable under the Applicable In-License and shall not include any annual maintenance fees, license fees, payments resulting from Acuitas' breach of an Applicable In-License or any other payment thereunder.
- 1.15 "Know-How" means all commercial, technical, scientific and other know-how and information, trade secrets, knowledge, technology, methods, processes, practices, formulae, instructions, skills, techniques, procedures, experiences, ideas, technical assistance, designs, drawings, assembly procedures, computer programs, specifications, data and results (including biological, chemical, pharmacological, toxicological, pharmaceutical, physical and analytical, preclinical, clinical, safety, manufacturing and quality control data and know-how, including study designs and protocols), in all cases, (a) to the extent Confidential Information of Acuitas, (b) whether or not patentable, and (c) provided by Acuitas to Moderna pursuant to the Development and Option Agreement.
- 1.16 "Licensed Product" means any product (a) that includes one (1) or more mRNA Constructs coding for the Licensed Target and (b) the Manufacture, use, sale, offer for sale or importation of which in or into a particular country is Covered by the Licensed Technology, as determined on a product-by-product and country-by-country basis.
- 1.17 "<u>Licensed Proprietary Technology</u>" means all Know-How, Patents and Materials and that (a) Cover LNP Technology (including the manufacture or use thereof), and (b) are owned by Acuitas or any of its Affiliates at the relevant point in time, and (c) that may be necessary or useful to Develop and Commercialize Licensed Products.
 - 1.18 "Licensed Target" means the Target identified on Appendix A hereto.
- 1.19 "<u>Licensed Technology</u>" means the Licensed Proprietary Technology and Licensed Third Party Technology.
- 1.20 "Licensed Third Party Technology" means any and all Know-How, Patents and Materials that (a) Cover LNP Technology (including the manufacture or use thereof), and (b) that are in-licensed by Acuitas or its Affiliates pursuant to the Applicable In-Licenses (including any extensions or expansions of the scope thereof), and (c) are Controlled at the applicable time by Acuitas or any of its Affiliates and (d) that may be necessary or useful to Develop and Commercialize Licensed Products..
- 1.21 "LNP In-Licenses" means all agreements entered into prior to the License Agreement Effective Date or at any time during the Term between Acuitas or its Affiliates and a Third Party

pursuant to which Acuitas or its Affiliates is granted a license or other rights to LNP Technology that may be necessary or useful to Develop and Commercialize Licensed Products.

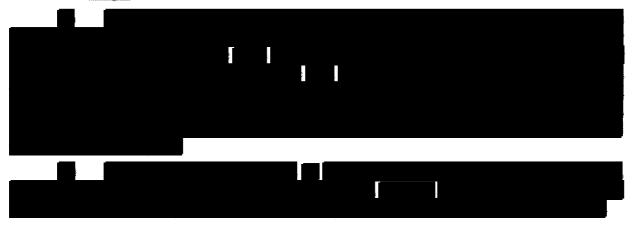


1.23 "<u>Manufacturing</u>" means the production, manufacture, processing, filling, finishing, packaging, labeling, shipping and holding of product or any intermediate thereof, including process development, process qualification and validation, scale-up, commercial manufacture and analytic development, product characterization, stability testing, quality assurance and quality control.



- 1.26 "Patent" means the rights and interests in and to all issued patents and pending patent applications in any country, including, without limitation, all provisional applications, substitutions, continuations, continuations-in-part, divisions, and renewals, all letters patent granted thereon, and all patents-of-addition, reissues, reexaminations and extensions or restorations by existing or future extension or restoration mechanisms, including, without limitation Supplementary Protection Certificates or the equivalent thereof.
- 1.27 "Patent Costs" means the reasonable, documented, out-of-pocket costs and expenses paid to outside legal counsel, and filing and maintenance expenses, actually and reasonably incurred by a Party in prosecuting and maintaining Patents and enforcing and defending them.
- 1.28 "Pending Claim" means, with respect to a particular country, any claim of a pending Patent application in such country that (a) has not been held revoked, unenforceable or invalid by a decision of a court or governmental agency of competent jurisdiction from which no further appeal is possible (other than to the United States Supreme Court), (b) has not been abandoned, disclaimed, denied or admitted to be invalid or unenforceable through reissue or disclaimer or otherwise in such country, and (c)
- 1.29 "Phase 1 Study" means a human clinical trial of a Licensed Product in any country, the primary purpose of which is the determination of safety and which may include the determination of pharmacokinetic and/or pharmacodynamic profiles in healthy individuals or patients.
- 1.30 "Phase 2 Study" means a human clinical trial of a Licensed Product in any country, and which is: (a) a study of dose exploration, dose response, duration of effect, kinetics or preliminary efficacy and safety study of a product in the target patient population, (b) a controlled dose-ranging clinical trial to evaluate further the efficacy and safety of such product in the target population and to define the optimal dosing regimen or (c) a clinical trial that Moderna refers to in a press release as a Phase II (or IIa or IIb) clinical trial or study.
- 1.31 "Phase 3 Study" means a human clinical trial of a Licensed Product in any country, and which is: (a) a controlled study of a product in patients of the efficacy and safety of such product which is prospectively designed to demonstrate statistically whether such product is effective and safe for use in a particular indication in a manner sufficient to obtain Regulatory Approval to market such product or (b) a clinical trial that Moderna refers to in a press release as a Phase III or registration clinical trial or pivotal study.
- 1.32 "Regulatory Approval" means, with respect to a country or extra-national territory, any and all approvals (including BLAs and MAAs), licenses, registrations or authorizations of any Regulatory Authority necessary in order to commercially distribute, sell or market a product in such country or some or all of such extra-national territory, excluding any pricing or reimbursement approvals.
- 1.33 "Regulatory Authority" means any national (e.g., the FDA), supra-national (e.g., the EMA), regional, state or local regulatory agency, department, bureau, commission, council or other governmental authority, in any jurisdiction in the world, involved in the granting of Regulatory Approval.

- 1.34 "Sublicensee" means any Third Party that is granted a sublicense as permitted by Section 3.5, either directly by Moderna or its Affiliates or indirectly by any other Sublicensee hereunder.
 - 1.35 "Target" means either:



1.36 "Territory" means worldwide.

1.37	"Valid Claim"	means, with	h respect	to a particul	ar country,	any	claim	of an	issued	and
unexpired F	atent in such	country that								٠

Definitions for each of the following terms are found in the body of this License Agreement as indicated below:

Defined Terms	Location
Acuitas Indemnitees	Section 10.6(a)
Competitive Infringement	Section 8.1
Indemnification Claim Notice	Section 10.6(c)
Indemnified Party	Section 10.6(c)
In-License Milestone Payments	Section 5.1
In-License Royalties	Section 5.1
Losses	Section 10.6(a)
Acuitas Milestone Event	Section 5.1
Acuitas Milestone Payment	Section 5.1
Moderna Indemnitees	Section 10.6(b)
Solely Owned IP	Section 6.1
Term	Section 11.1
Third Party Claims	Section 10.6(a)

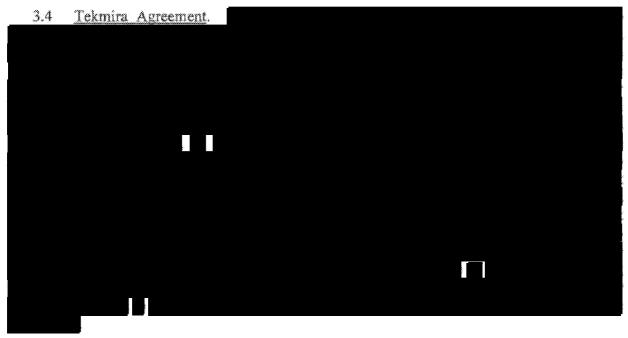
2. Development and Commercialization.

2.1 <u>Development</u>. Moderna shall have sole responsibility for, and shall bear all its costs of conducting, all Development and Commercialization of Licensed Products (including filing for and obtaining all required Regulatory Approvals). As between the Parties, all such Regulatory Approvals shall be obtained by and in the name of Moderna (or its Affiliates or Sublicensees).

3. License Grants.

3.1 Licenses by Acuitas.

- (a) Licensed Technology. Subject to the terms and conditions of this License Agreement, Acuitas and its Affiliates hereby grant to Moderna and its Affiliates (a) a non-exclusive, non-transferrable (other than pursuant to Section 12.11) license, with the right to sublicense only as permitted by Section 3.5(b), under the Licensed Technology, to Develop and Commercialize Licensed Products in the Field of Use in the Territory.
- 3.2 <u>No Obligation to Provide Know-How.</u> The Parties acknowledge and agree that neither Acuitas nor any of its Affiliates is obligated hereunder to, or will, absent prior written agreement by the Parties, transfer to Moderna or its Affiliates any Know-How or materials.
- of Patents that are added to the Licensed Technology following the Effective Date or any Patents that have been abandoned or discontinued in accordance with the terms of this License Agreement. Appendix C shall be automatically updated to include any such added Patents provided that, with written notice to Acuitas, Moderna may elect to exclude any particular Patents from the Licensed Technology. Following any such notice by Moderna, the applicable Patents that Moderna identifies for exclusion from this License Agreement will no longer be licensed to Moderna hereunder, and Moderna shall not have any obligations hereunder with respect to such Patent.



3.5 Sublicensing Rights.

(a) Transfer. The licenses granted in Sections 3.1 are transferable only upon a permitted assignment of this License Agreement in accordance with Section 12.11.

- (b) Moderna Sublicenses. The licenses granted in Section 3.1 may be sublicensed, in full or in part, by Moderna or its Affiliates or Sublicensees by a written agreement to Third Parties (with the right to sublicense through multiple tiers), provided, that:
- (i) Each sublicense will be in writing and on terms consistent with and subject to the terms of this Agreement,
- (ii) Moderna will provide Acuitas with a copy of any sublicense agreement with a Sublicensee within of execution thereof, which sublicense agreement may be redacted as necessary to protect commercially sensitive information and shall be treated as Moderna Confidential Information hereunder;
- (iii) Moderna will be responsible for any and all obligations of such Sublicensee as if such Sublicensee were "Moderna" hereunder; and
- (iv) Any sublicense granted by Moderna to any rights licensed to it hereunder shall terminate immediately upon the termination of the license from Acuitas to Moderna and its Affiliates with respect to such rights, provided that such sublicensed rights shall not terminate if, as of the effective date of such termination pursuant to Sections 11.2, 11.3(a) or 11.4, a Sublicensee is not in material default of its obligations under its sublicense agreement, and within days of such termination the Sublicensee agrees in writing to be bound directly to Acuitas under a license agreement substantially similar to this License Agreement with respect to the rights sublicensed hereunder, substituting such Sublicensee for Moderna.
- 3.6 <u>License Limitations</u>. No licenses or other rights are granted by Acuitas hereunder to use any trademark, trade name, trade dress or service mark owned or otherwise Controlled by Acuitas or any of its Affiliates. All licenses and other rights are or shall be granted only as expressly provided in this License Agreement, and no other licenses or other rights is or shall be created or granted by either Party hereunder by implication, estoppel or otherwise.

4. Applicable In-Licenses.

Applicable In-Licenses. The Applicable In-Licenses as of the License Agreement Effective Date are listed in Appendix B. If during the Term Acuitas or its Affiliates enters into any Third Party In-License pursuant to which Acuitas or its Affiliates in-licenses any Patents or Know-How Covering LNP Technology that is Controlled by Acuitas or its Affiliates, Acuitas will notify Moderna of same and provide Moderna with a copy of such Third Party In-License (which may be redacted as necessary to protect commercially sensitive information of Acuitas that is not relevant to the grant of a sublicense to Moderna). Moderna shall have the option of including any such Third Party In-License within the scope of this License Agreement by providing Acuitas with notice of same, provided that (a) such notice is provided to Acuitas within of Moderna's receipt of notice from Acuitas, or (b) if such notice is provided to Acuitas later than of Moderna's receipt of notice from Acuitas, the LNP Technology that is in-licensed by Acuitas or its Affiliates pursuant to the Third Party In-License is still Controlled by Acuitas or its Affiliates for the purposes of granting a sublicense to Moderna hereunder. Appendix B will automatically be updated to include such Third Party In-License added in accordance with subsections (a) or (b) above and the provisions of this License Agreement applicable to Applicable In-Licenses, including Section 5.1, will apply with respect to such Third Party In-License.

4.2 <u>Maintenance of Applicable In-Licenses</u>. Acuitas (a) will duly perform and observe all of its obligations under the Applicable In-Licenses in all material respects (and in all respects if the failure to do so would give rise to a right of termination on the part of the licensor) and maintain

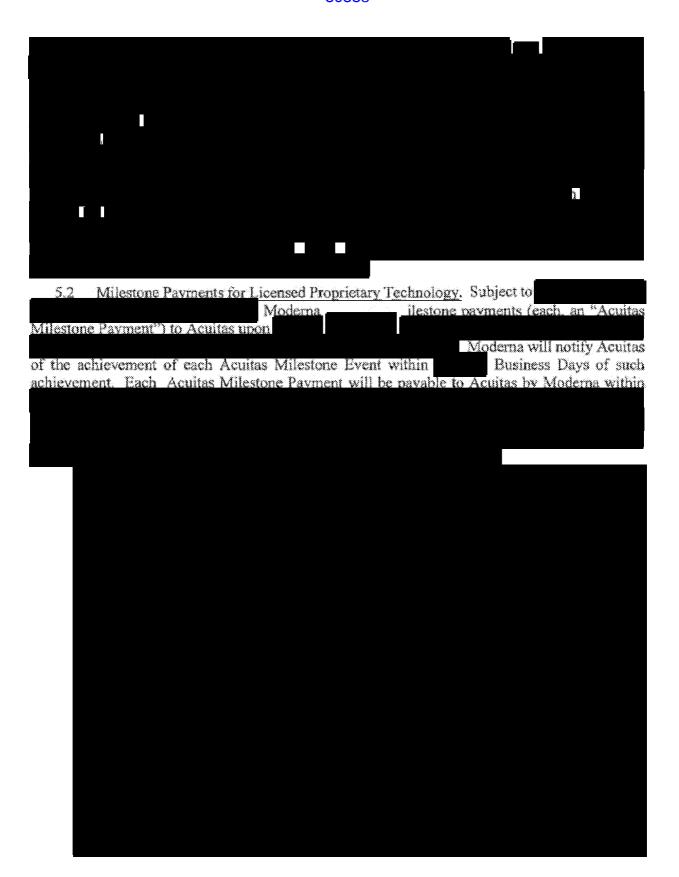


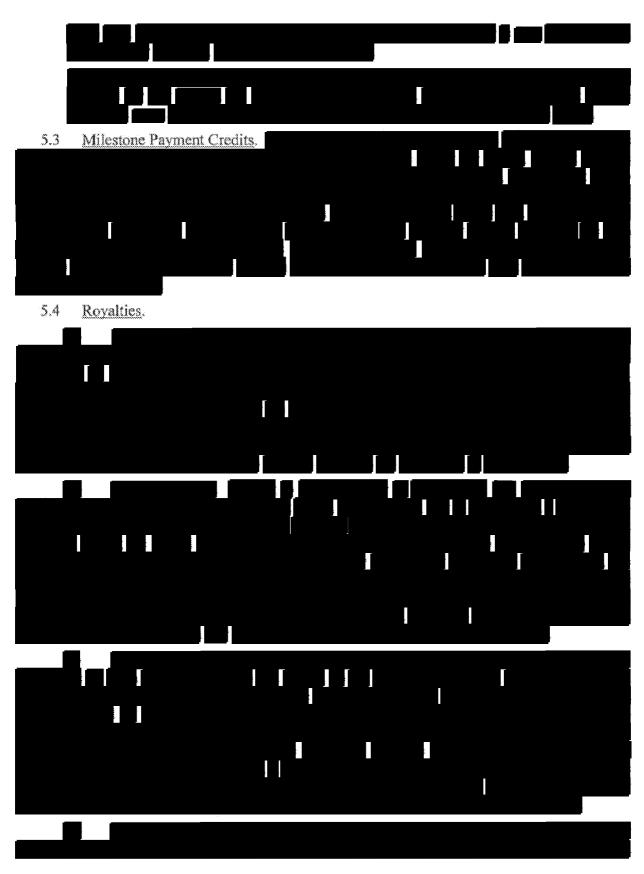
4.3 <u>Applicable In-License Requirements</u>. Moderna will abide, and will cause all its Affiliates and applicable Sublicensees to abide, by all requirements of each Applicable In-License in all material respects, to the extent applicable to sublicensees thereunder and to the extent disclosed by Acuitas to Moderna.

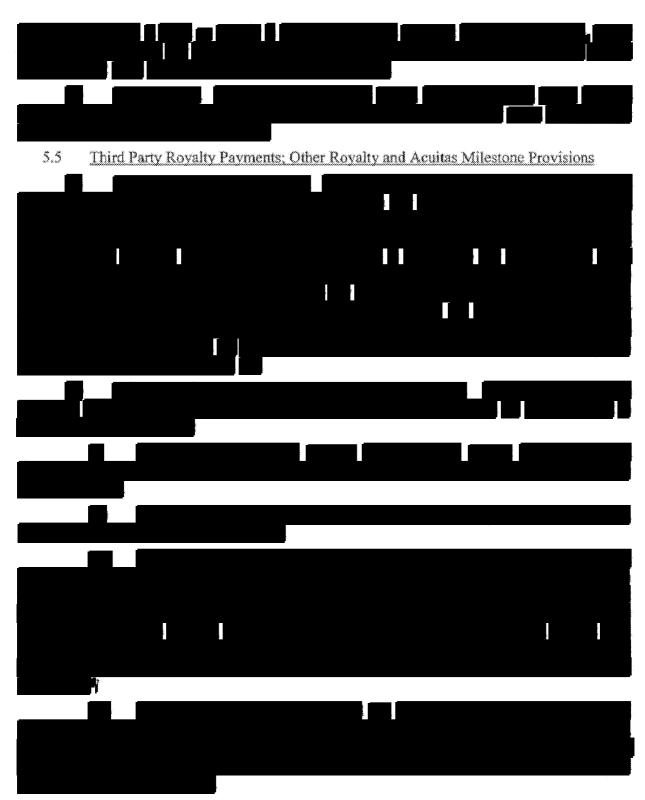


5. Payments and Royalties.









5.6 Payment Terms.

(a) Manner of Payment. All payments to be made by Moderna hereunder will be made in U.S. dollars by wire transfer to such bank account as Acuitas may designate.

- (b) Records and Audits. Moderna shall keep, and shall cause each of its Affiliates and Sublicensees, as applicable, to keep adequate books and records of accounting for the purpose of calculating all royalties payable to Acuitas hereunder. For the next following the end of the calendar year to which each shall pertain, such books and records of accounting (including those of Moderna's Affiliates and Sublicensees, as applicable) shall be kept at each of their principal place of business and shall be open for inspection at reasonable times and upon reasonable notice by an independent certified accountant selected by Acuitas, and which is reasonably acceptable to Moderna, for the sole purpose of inspecting the royalties due to Acuitas under this License Agreement. In no event shall such inspections be conducted hereunder more frequently than once Such accountant must have executed and delivered to Moderna and its Affiliates or Sublicensees, as applicable, a confidentiality agreement as reasonably requested by Moderna, which shall include provisions limiting such accountant's disclosure to Acuitas to only the results and basis for such results of such inspection. The results of such inspection, if any, shall be binding on both Parties. Any underpayments shall be paid by Moderna within of notification of the results of such inspection. overpayments shall be fully creditable against amounts payable in subsequent payment periods. Acuitas shall pay for such inspections, except that in the event there is any upward adjustment in aggregate royalties payable for any calendar year shown by such inspection of more than of the amount paid, Moderna shall reimburse Acuitas for any reasonable out-ofpocket costs of such accountant.
- or 5.4, Moderna shall furnish to Acuitas a written report for each Calendar Quarter, showing the amount of Net Sales of Licensed Products and royalty due for such Calendar Quarter. Reports shall be provided within of the end of the quarter for Net Sales generated by Moderna and its Affiliates, and within of the end of the end of the quarter for Net Sales generated by Sublicensees. Royalty payments for each Calendar Quarter shall be due at the same time as such written report for the Calendar Quarter.



treated as Confidential Information of Moderna but may be disclosed by Acuitas as required under the Applicable In-Licenses.

(d) Currency Exchange. With respect to Net Sales invoiced in U.S. dollars, the Net Sales and the amounts due to Acuitas hereunder will be expressed in U.S. dollars. With respect to Net Sales invoiced in a currency other than U.S. dollars, payments will be calculated based on standard methodologies employed by Moderna or its Affiliates or Sublicensees for consolidation purposes for the Calendar Quarter for which remittance is made for royalties.

- (e) Taxes. Moderna may withhold from payments due to Acuitas amounts for payment of any withholding tax that is required by Law to be paid to any taxing authority with respect to such payments. Moderna will provide Acuitas all relevant documents and correspondence, and will also provide to Acuitas any other cooperation or assistance on a reasonable basis as may be necessary to enable Acuitas to claim exemption from such withholding taxes and to receive a refund of such withholding tax or claim a foreign tax credit. Moderna will give proper evidence from time to time as to the payment of any such tax. The Parties will cooperate with each other in seeking deductions under any double taxation or other similar treaty or agreement from time to time in force. Such cooperation may include Moderna making payments from a single source in the U.S., where possible. Apart from any such permitted withholding and those deductions expressly included in the definition of Net Sales, the amounts payable by Moderna to Acuitas hereunder will not be reduced on account of any taxes, charges, duties or other levies.
- (f) Blocked Payments. In the event that, by reason of applicable Law in any country, it becomes impossible or illegal for Moderna or its Affiliates or Sublicensees to transfer, or have transferred on its behalf, payments owed to Acuitas hereunder, Moderna will promptly notify Acuitas of the conditions preventing such transfer and such payments will be deposited in local currency in the relevant country to the credit of Acuitas in a recognized banking institution designated by Acuitas or, if none is designated by Acuitas within a period of days, in a recognized banking institution selected by Moderna or its Affiliate or Sublicensee, as the case may be, and identified in a written notice given to Acuitas.
- (g) Interest Due. If any payment due to Acuitas under this License Agreement is overdue (and is not subject to a good faith dispute), then Acuitas will pay interest thereon (before and after any judgment) at an annual rate (but with interest accruing on a daily basis) of the lesser
- (h) Mutual Convenience of the Parties. The royalty and other payment obligations set forth hereunder have been agreed to by the Parties for the purpose of reflecting and advancing their mutual convenience, including the ease of calculating and paying royalties and other amounts to Acuitas.

6. Ownership and Inventorship of IP.

6.1 <u>Solely-Owned IP</u>. As between the Parties, each Party will own and retain all right, title and interest in and to any and all Know-How and Patents arising therefrom that are discovered, created, conceived, developed or reduced to practice solely by or on behalf of such Party under or in connection with this License Agreement ("<u>Solely Owned IP</u>"). Subject to the licenses hereunder and the other terms and conditions of this License Agreement, each Party will be solely responsible for the Prosecution and Maintenance, and the enforcement and defense, of any Patents within its Solely Owned IP.

7. Patent Prosecution and Maintenance.

7.1 <u>Generally</u>. As between the Parties, Acuitas will have the sole right to prosecute and maintain Patents within the Licensed Proprietary Technology. Acuitas will regularly provide Moderna with copies of all applications for Patents within the Licensed Proprietary Technology, and all other material submissions and correspondence with any Patent authorities regarding such

Patents, in sufficient time to allow for review and comment by Moderna. In addition, Acuitas will provide Moderna and its counsel with an opportunity to consult with Acuitas and its counsel regarding prosecution and maintenance of any such Patents, and Acuitas will consider in good faith all reasonable comments timely made by Moderna and its counsel.

- 7.2 Election Not to Prosecute or Maintain or Pay Patent Costs. If Acuitas elects not (i) to prosecute or maintain any Patents within the Licensed Proprietary Technology in any particular country before the applicable filing deadline or continue such activities once filed in a particular country, or (ii) to pay the Patent Costs associated with prosecution or maintenance of any Patents within the Licensed Proprietary Technology then in each such case Acuitas will so notify Moderna, promptly in writing and in good time to enable Acuitas to meet any deadlines by which an action must be taken to preserve such Patent in such country, if Moderna so requests. Upon receipt of each such notice by Acuitas, Moderna will have the right, but not the obligation, to notify Acuitas in writing on a timely basis that Acuitas should continue the prosecution or maintenance of such Patent, at Moderna's expense and thereafter,
- 7.3 Third Party Rights. To the extent that a Third Party licensor of Acuitas has provided Acuitas or its Affiliates with rights to prosecute or maintain and/or defend any Patent within the Licensed Third Party Technology licensed to Moderna hereunder, or to review or comment with respect to any such maintenance or prosecution activities, Acuitas will provide Moderna with the opportunity to consult with Acuitas and its counsel in connection therewith and will consider in good faith Moderna's comments to the extent permitted under such Applicable In-License.
- 7.4 Patent Extensions. If any election for Patent term restoration or extension, supplemental protection certificate or any of their equivalents may be made with respect to any Patent within the Licensed Proprietary Technology, after consultation with Moderna, the Parties will discuss and seek to reach mutual agreement whether or not to take such action. If the Parties are not able to reach mutual agreement, (a) Moderna will have the sole right to make the final decision whether or not to seek such Patent term restoration or extension, supplemental protection certificate or any of their equivalents with respect to Patents within the Licensed Proprietary Technology that cover Licensed Product and no product licensed to any other licensee of Acuitas or Commercialized by Acuitas, and (b) Acuitas will have the sole right to make the final decision whether or not to seek such Patent term restoration or extension, supplemental protection certificate or any of their equivalents with respect to all other Patents within the Licensed Proprietary Technology that claim Licensed Products and other products licensed by Acuitas or Commercialized by Acuitas.
- 7.5 Regulatory Exclusivity Periods. With respect to any Patent listings required for any regulatory exclusivity periods for Licensed Products the Parties will mutually agree on which Patents within the Licensed Technology to list, provided that if the Parties are not able to agree, Moderna will have the right to make the final decision with respect to Patents within the Licensed Proprietary Technology that cover Licensed Product and no product licensed to any other licensee of Acuitas or Commercialized by Acuitas, and provided further that the exercise of such right by Moderna will not increase or otherwise change the rights or obligations of the Parties hereunder.
- 7.6 <u>Cooperation</u>. Each Party will reasonably cooperate with the other Party in the prosecution and maintenance of Patents within the Licensed Technology. Such cooperation

includes promptly executing all documents, or requiring inventors, subcontractors, employees and consultants and agents of Moderna and Acuitas and their respective Affiliates and Sublicensees to execute all documents, as reasonable and appropriate so as to enable the prosecution and maintenance of any such Patents in any country.

8. Patent Enforcement and Defense.

8.1 Notice. Each Party will promptly notify, in writing, the other Party upon learning of any actual or suspected Competitive Infringement of any Patents within the Licensed Technology by a Third Party, or of any claim of invalidity, unenforceability, or non-infringement of any Patents within the Licensed Technology, and will, along with such notice, supply the other Party with any evidence in its possession pertaining thereto. For purposes of this License Agreement, "Competitive Infringement" means

8.2 Enforcement and Defense.

- (a) Patents within the Licensed Technology and Competitive Infringement.
- (i) As between the Parties, Acuitas will have the first right, but not the obligation, to seek to abate any Competitive Infringement of the Patents within the Licensed Proprietary Technology by a Third Party, or to file suit against any such Third Party for such Competitive Infringement of Acuitas-Owned Technology, and, if permitted pursuant to an Applicable In-License, Licensed Third Party Technology. If Acuitas does not take steps to abate such Competitive Infringement, or file suit to enforce the Patents within the Licensed Technology against such Third Party with respect to such Competitive Infringement, within a commercially reasonably time, Moderna will have the right (but not the obligation) to take action to enforce the Patents within the Licensed Proprietary Technology that cover Licensed Product and no product licensed to any other licensee of Acuitas or Commercialized by Acuitas against such Third Party for such Competitive Infringement. The controlling Party will pay all its Patent Costs incurred for such enforcement.
- (ii) Neither Party will exercise any of its enforcement rights under this Section 8.2(a) without first consulting with the other Party, provided that this consultation requirement will not limit either Party's rights under this Section 8.2(a).
- (b) Defense. As between the Parties, Acuitas will have the first right, but not the obligation, to defend against a declaratory judgment action or other action challenging any Patents within the Licensed Proprietary Technology, other than with respect to any action or counter claims by a Third Party in response to an enforcement action brought by Moderna alleging infringement of any Patents within the Licensed Technology, which defense will be controlled by the Party controlling such enforcement action. If Acuitas does not take steps to defend within a commercially reasonably time, or elects not to continue any such defense (in which case it will promptly provide notice thereof to Moderna), then Moderna will have the right (but not the obligation) to defend any such Patent within the Licensed Proprietary Technology that cover Licensed Product and no product licensed to any other licensee of Acuitas or Commercialized by Acuitas.
- (c) Withdrawal, Cooperation and Participation. With respect to any infringement or defensive action identified above in this Section 8.2:

- (i) If the controlling Party ceases to pursue or withdraws from such action, it will promptly notify the other Party (in good time to enable the other Party to meet any deadlines by which any action must be taken to preserve any rights in such infringement or defensive action) and such other Party may substitute itself for the withdrawing Party and proceed under the terms and conditions of this Section 8.2.
- (ii) The non-controlling Party will cooperate with the Party controlling any such action (as may be reasonably requested by the controlling Party), including (A) providing access to relevant documents and other evidence, (B) making its and its Affiliates and licensees and Sublicensees and all of their respective employees, subcontractors, consultants and agents available at reasonable business hours and for reasonable periods of time, but only to the extent relevant to such action, and (C) if necessary, by being joined as a party, subject for this clause (C) to the controlling Party agreeing to indemnify such non-controlling Party for its involvement as a named party in such action and paying those Patent Costs incurred by such Party in connection with such joinder. The Party controlling any such action will keep the other Party updated with respect to any such action, including providing copies of all documents received or filed in connection with any such action.
- (iii) Each Party will have the right to participate or otherwise be involved in any such action controlled by the other Party, in each case at the participating Party's sole cost and expense. If a Party elects to so participate or be involved, the controlling Party will provide the participating Party and its counsel with an opportunity to consult with the controlling Party and its counsel regarding the prosecution of such action (including reviewing the contents of any correspondence, legal papers or other documents related thereto), and the controlling Party will take into account reasonable requests of the participating Party regarding such enforcement or defense.
- (d) Settlement. Neither Party will settle or consent to an adverse judgment in any action described in this Section 8.2 and controlled by such Party, including any judgment which affects the scope, validity or enforcement of any Patents within the Licensed Technology involved therewith, without the prior written consent of the other Party (such consent not to be unreasonably withheld or delayed).
- (e) Damages. Unless otherwise agreed by the Parties, all monies recovered upon the final judgment or settlement of any action described in Section 8.2(a) or any action described in Section 8.2(b) controlled by Moderna will be used first to reimburse each of the Parties, for each of their out-of-pocket costs and expenses relating to the action, with the balance of any such recovery to be divided as follows:



9. Confidentiality.

- 9.1 <u>Confidential Information</u>. Each Party ("<u>Disclosing Party</u>") may disclose to the other Party ("<u>Receiving Party</u>"), and Receiving Party may acquire during the course and conduct of activities under this License Agreement, certain proprietary or confidential information of Disclosing Party in connection with this License Agreement. The term "<u>Confidential Information</u>" means (i) all Materials and (ii) all ideas and information of any kind, whether in written, oral, graphical, machine-readable or other form, whether or not marked as confidential or proprietary, which are disclosed or made available by or on behalf of the Disclosing Party to the Receiving Party, including any of the foregoing of Third Parties.
- Restrictions. During the Term and for thereafter, Receiving Party will keep all Disclosing Party's Confidential Information in confidence with the same degree of care with which Receiving Party holds its own confidential information, but in no event less than reasonable care. Receiving Party will not use Disclosing Party's Confidential Information except for in connection with the performance of its obligations and exercise of its rights under this License Agreement. Receiving Party has the right to disclose Disclosing Party's Confidential Information without Disclosing Party's prior written consent to Receiving Party's Affiliates, Approved Partners, and each of their employees, subcontractors, consultants or agents who have a need to know such Confidential Information in order to perform its obligations and exercise its rights under this License Agreement and who are required to comply with the restrictions on use and disclosure that are no less restrictive than those set forth in this Section 9.2. Receiving Party assumes responsibility for those entities and persons maintaining Disclosing Party's Confidential Information in confidence and using same only for the purposes described herein.
- 9.3 Exceptions. Receiving Party's obligation of nondisclosure and the limitations upon the right to use the Disclosing Party's Confidential Information will not apply to the extent that Receiving Party can demonstrate that the Disclosing Party's Confidential Information: (i) was known to Receiving Party or any of its Affiliates prior to the time of disclosure by the Disclosing Party; (ii) is or becomes public knowledge through no fault or omission of Receiving Party or any of its Affiliates; (iii) is obtained on a non-confidential basis by Receiving Party or any of its Affiliates from a Third Party who to Receiving Party's knowledge is lawfully in possession thereof and under no obligation of confidentiality to Disclosing Party; or (iv) has been independently developed by or on behalf of Receiving Party or any of its Affiliates without the aid, application or use of Disclosing Party's Confidential Information.

- 9.4 <u>Permitted Disclosures</u>. Receiving Party may disclose Disclosing Party's Confidential Information to the extent (and only to the extent) such disclosure is reasonably necessary in the following instances:
- (a) in order to comply with applicable Law (including any securities Law or regulation or the rules of a securities exchange) or with a legal or administrative proceeding;
- (b) in connection with prosecuting or defending litigation, regulatory approvals and other regulatory filings and communications, and filing, prosecuting and enforcing Patents in connection with Receiving Party's rights and obligations pursuant to this License Agreement; and
- (c) in connection with exercising its rights hereunder, to its Affiliates; permitted acquirers or assignees; investment bankers, investors and lender; and in the case of Moderna, to its Approved Partners;.
- provided that (1) with respect to Sections 9.4(a) or 9.4(b), where reasonably possible, Receiving Party will notify Disclosing Party of Receiving Party's intent to make any disclosure pursuant thereto sufficiently prior to making such disclosure so as to allow Disclosing Party adequate time to take whatever action it may deem appropriate to protect the confidentiality of the information to be disclosed, and (2) with respect to Section 9.4(c), each of those named people and entities are required to comply with the restrictions on use and disclosure in Section 9.2 (other than investment bankers, investors and lenders, which must be bound prior to disclosure by commercially reasonable obligations of confidentiality).
- 9.5 Terms of this License Agreement: Publicity. The Parties agree that the existence and terms of this License Agreement will be treated as Confidential Information of both Parties, and thus may be disclosed only as permitted by Section 9.4. Except as required by Law, each Party agrees not to issue any press release or public statement disclosing information relating to the existence of this License Agreement or the transactions contemplated hereby or the terms hereof without the prior written consent of the other Part.

10. Warranties; Limitations of Liability; Indemnification.

- 10.1 Representations and Warranties. Each Party represents and warrants to the other as of the License Agreement Effective Date that it has the legal right and power to enter into this License Agreement, to extend the rights and licenses granted or to be granted to the other in this License Agreement, and to fully perform its obligations hereunder.
- 10.2 <u>Additional Representations and Warranties of Acuitas</u>. Except as set forth in <u>Schedule 10.2</u>, Acuitas represents and warrants to Moderna that, as of the License Agreement Effective Date:
- (a) Licensed Technology. Appendix C sets forth a complete and accurate list of all Patents included in the Licensed Technology, indicating the owner, licensor and/or co-owner(s), if applicable. Acuitas Controls the Patents listed on Appendix C and the Know-How within the Licensed Technology, and is entitled to grant the licenses specified herein. To Acuitas' knowledge, the Patents listed on Appendix C have been procured or are being procured from the respective Patent offices in accordance with applicable Law. None of the Patents included in the Licensed Technology is or has been involved in any opposition, cancellation, interference, reissue or reexamination proceeding, and to Acuitas' knowledge no Licensed Technology is the subject

of any judicial, administrative or arbitral order, award, decree, injunction, lawsuit, proceeding or stipulation. Neither Acuitas nor any of its Affiliates has received any notice alleging that the Patents in the Licensed Technology are invalid or unenforceable, or challenging Acuitas' ownership of or right to use any such rights. In the event that Acuitas or its Affiliates directly or indirectly, grants, assign, licenses, sublicenses, encumbers or otherwise transfers (each, a "Transfer") to any Third Party any right, title or interest in or to the Licensed Proprietary Technology, such Transfer will be subject to the rights and licenses granted to Moderna and its Affiliates herein.

(b) Third Party Agreements. The Applicable In-Licenses are valid and binding obligations of Acuitas and, to the knowledge of Acuitas, the applicable licensor, enforceable against Acuitas and, to the Knowledge of Acuitas, the applicable licensor, in accordance with their terms, except as may be limited by general principles of equity (regardless of whether considered in a proceeding at law or in equity) and by applicable bankruptcy, insolvency, moratorium and other similar Laws of general application relating to or affecting creditors' rights generally.



- (c) Patents. To Acuitas' knowledge, the Patents listed on Appendix C have been procured or are being procured from the respective patent offices in accordance with applicable Law. None of the Patents included in the Licensed Technology is or has been involved in any opposition, cancellation, interference, reissue or reexamination proceeding, and no Licensed Technology is the subject of any judicial, administrative or arbitral order, award, decree, injunction, lawsuit, proceeding or stipulation. Neither Acuitas nor any of its Affiliates has received any notice alleging that the Patents in the Licensed Technology are invalid or unenforceable, or challenging Acuitas' ownership of or right to use any such rights.
- (d) Encumbrances. Except for the Third Party In-Licenses, Acuitas and its Affiliates are not subject to any payment obligations to Third Parties as a result of the execution or performance of this License Agreement. Neither Acuitas nor any of its Affiliates has granted any liens or security interests on the Licensed Technology and the Licensed Technology is to Acuitas' knowledge free and clear of any mortgage, pledge, claim, security interest, covenant, easement,

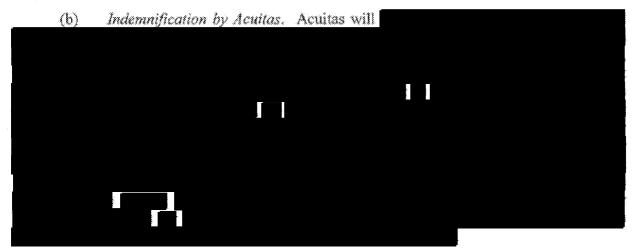
encumbrance, lien or charge of any kind. The foregoing shall not apply to any option or license agreement entered into by Acuitas prior to the Effective Date.

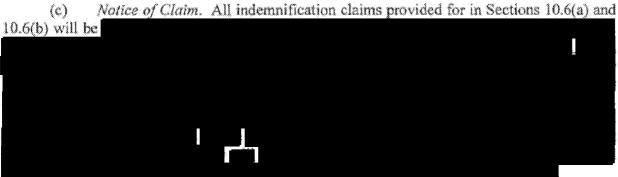
- (e) No Conflicts. The execution, delivery and performance by Acuitas of this License Agreement and the consummation of the transactions contemplated hereby will not result in any violation of, conflict with, result in a breach of or constitute a default under any understanding, contract or agreement to which Acuitas is a party or by which it is bound.
- (f) No Proceedings. There is no action, suit, proceeding or investigation pending or, to the knowledge of Acuitas, currently threatened in writing against or affecting Acuitas that questions the validity of this License Agreement or the right of Acuitas to enter into this License Agreement or consummate the transactions contemplated hereby.
- (g) Infringement. Neither Acuitas nor any of its Affiliates has received any notice of any claim that any Patent, Know-How or other intellectual property owned or controlled by a Third Party would be infringed or misappropriated by the Licensed Technology in the production, use, research, development, manufacture or commercialization of Licensed Product.
- 10.3 <u>Disclaimers</u>. Without limiting the respective rights and obligations of the Parties expressly set forth herein, each Party specifically disclaims any guarantee that any Licensed Product will be successful, in whole or in part. EXCEPT AS OTHERWISE EXPRESSLY PROVIDED IN THIS LICENSE AGREEMENT, THE PARTIES MAKE NO REPRESENTATIONS AND EXTEND NO WARRANTY OF ANY KIND, EITHER EXPRESS OR IMPLIED.
- 10.4 No Consequential Damages. NOTWITHSTANDING ANYTHING IN THIS AGREEMENT OR OTHERWISE, NEITHER PARTY WILL BE LIABLE TO THE OTHER OR ANY THIRD PARTY WITH RESPECT TO ANY SUBJECT MATTER OF THIS AGREEMENT FOR ANY INDIRECT, PUNITIVE, SPECIAL OR CONSEQUENTIAL DAMAGES, EVEN IF SUCH PARTY HAS BEEN INFORMED OR SHOULD HAVE KNOWN OF THE POSSIBILITY OF SUCH DAMAGES; PROVIDED THAT THIS SECTION 10.4 WILL NOT APPLY TO BREACHES OF A PARTY'S CONFIDENTIALITY OBLIGATIONS OR THE PARTIES' INDEMNIFICATION RIGHTS AND OBLIGATIONS UNDER SECTION 10.6.
- 10.5 <u>Performance by Others</u>. The Parties recognize that each Party may perform some or all of its obligations under this License Agreement through Affiliates and permitted subcontractors provided, however, that each Party will remain responsible and liable for the performance by its Affiliates and permitted subcontractors and will cause its Affiliates and permitted subcontractors to comply with the provisions of this License Agreement in connection therewith.

10.6 Indemnification.

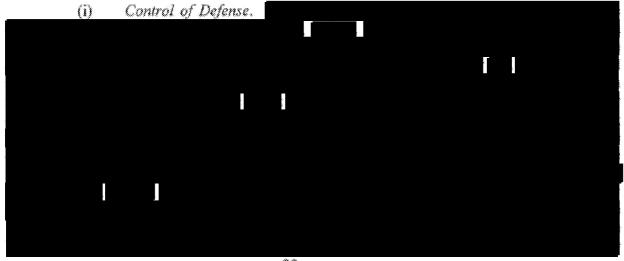
(a) Indemnification by Moderna. Moderna will indemnify Acuitas, its Affiliates and their respective directors, officers, employees, Third Party licensors and agents, and their respective successors, heirs and assigns (collectively, "Acuitas Indemnitees"), and defend and save each of them harmless, from and against any and all losses, damages, liabilities, costs and expenses (including reasonable attorneys' fees and expenses) (collectively, "Losses") in connection with any and all suits, investigations, claims or demands of Third Parties (collectively, "Third Party Claims") against the Acuitas Indemnitees arising from or occurring as a result of: (i) the material breach by Moderna of any term of this License Agreement; (ii) any gross negligence or willful misconduct on the part of Moderna in performing its obligations under this License Agreement;

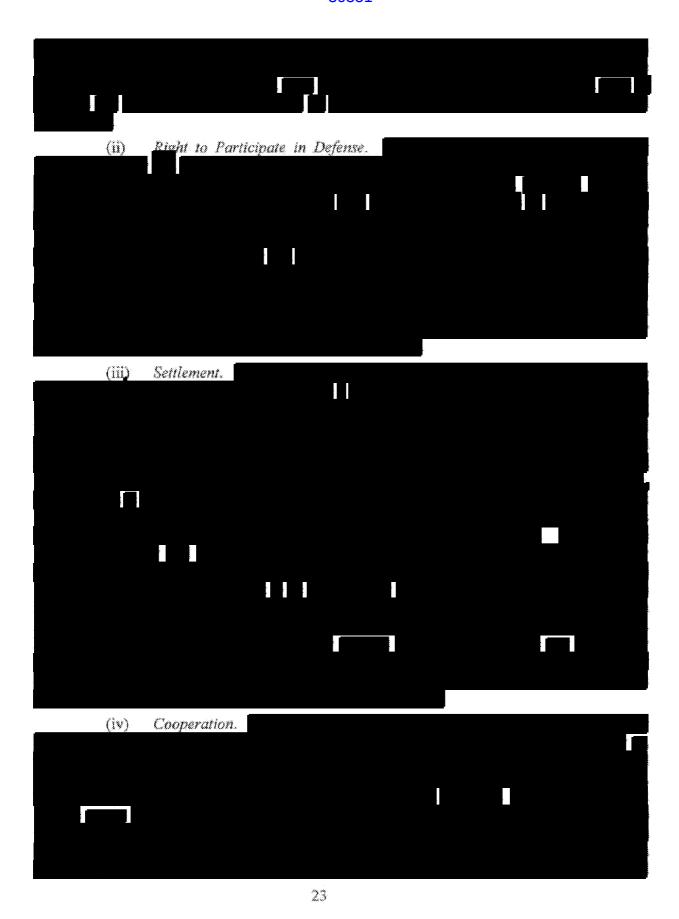
or (iii) the Development or Commercialization by or on behalf of Moderna or any of its Affiliates or Sublicensees of Licensed Product, except in each case for those Losses for which Acuitas has an obligation to indemnify Moderna pursuant to Section 10.6(b), as to which Losses each Party will indemnify the other to the extent of their respective liability; provided, however, that Moderna will not be obligated to indemnify Acuitas Indemnitees for any Losses to the extent that such Losses arise as a result of gross negligence or willful misconduct on the part of an Acuitas Indemnitee.





(d) Defense, Settlement, Cooperation and Expenses.







Insurance. Each Party will maintain at its sole cost and expense, an adequate liability insurance or self-insurance program (including product liability insurance) to protect against potential liabilities and risk arising out of activities to be performed under this License Agreement, and any agreement related hereto and upon such terms (including coverages, deductible limits and self-insured retentions) as are customary in the U.S. pharmaceutical industry for the activities to be conducted by such Party under this License Agreement. Subject to the preceding sentence, such liability insurance or self-insurance program will insure against all types of liability, including personal injury, physical injury or property damage arising out of the manufacture, sale, use, distribution or marketing of Licensed Product. The coverage limits set forth herein will not create any limitation on a Party's liability to the other under this License Agreement.

11. Term and Termination.

Date and, unless sooner terminated in accordance with the terms hereof or by mutual written consent, will continue on a country-by-country basis, until there are no more payments owed Acuitas on Licensed Product in such country (the longest such period of time for any Licensed Product hereunder, the "Term"). Upon there being no more such payments hereunder for any such Licensed Product in such country, the licenses contained in Section 3.1 for such Licensed Product will become fully paid up and will remain non-exclusive and in effect with respect to such Licensed Product in such country.

11.2 Termination by Acuitas.

(a) Breach. Acuitas will have the right to terminate this License Agreement in full upon delivery of written notice to Moderna in the event of any material breach by Moderna of any terms and conditions of this License Agreement, provided that such termination will not be effective if such breach, has been cured within days after written notice thereof is given by Acuitas to Moderna specifying the nature of the alleged breach.

11.3 Termination by Moderna.

- (a) Breach. Moderna will have the right to terminate this License Agreement in full upon delivery of written notice to Acuitas in the event of any material breach by Acuitas of any terms and conditions of this License Agreement, provided that such termination will not be effective if such breach has been cured within days after written notice thereof is given by Moderna to Acuitas specifying the nature of the alleged breach.
- (b) Discretionary Termination. Moderna will have the right to terminate this License Agreement in full at its discretion for any reason by delivering written notice to Acuitas, such termination to be effective days following the date of such notice.

(c) Alternative to Termination Under Section 11.3(a). If Moderna has the right to terminate this License Agreement under Section 11.3(a) as a result of a material breach by Acuitas (including following expiration of all applicable cure periods thereunder) that fundamentally impairs the value of Moderna's rights hereunder with respect to the Licensed Target, then Moderna may, in lieu of exercising such termination right, elect by written notice to Acuitas before the end of such applicable cure period to have this License Agreement continue in full force and effect for the Term, provided that the following will apply:

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11.4 Termination Upon Bankruptcy.

- (a) Termination Right. Either Party may terminate this License Agreement if, at any time, the other Party will file in any court or agency pursuant to any statute or regulation of any state, country or jurisdiction, a petition in bankruptcy or insolvency or for reorganization or for an arrangement or for the appointment of a receiver or trustee of that Party or of its assets, or if the other Party proposes a written agreement of composition or extension of its debts, or if the other Party will be served with an involuntary petition against it, filed in any insolvency proceeding, and such petition will not be dismissed within days after the filing thereof, or if the other Party will propose or be a Party to any dissolution or liquidation, or if the other Party will make an assignment for the benefit of its creditors.
- (b) Consequences of Bankruptcy. All rights and licenses granted under or pursuant to this License Agreement by Acuitas or its Affiliates are, and will otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code, licenses of right to "intellectual property" as defined under Section 101 of the U.S. Bankruptcy Code. The Parties agree that Moderna and its Affiliates and Sublicensees, as licensees of such rights under this License Agreement, will retain and may fully exercise all of their rights and elections under the U.S. Bankruptcy Code and any foreign counterparts thereto subject to the payment of amounts provided for herein.
- 11.5 <u>Effects of Termination</u>. Upon termination (but not expiration pursuant to Section 11.1) of this License Agreement for any reason:

- (a) Cessation of Rights. Except as otherwise expressly provided herein, all rights and licenses granted by Acuitas to Moderna in Section 3.1 will terminate, and Moderna and its Affiliates and Sublicensees will cease all use of Licensed Technology.
- (b) Country Termination. If this License Agreement is terminated only with respect to a specific country or a specific Licensed Product pursuant to Section 11.2(a), the provisions of this Section 11.5 will apply only with respect to such terminated country and such Licensed Product.
- 11.6 <u>Survival</u>. In addition to the termination consequences set forth in Section 11.5, the following provisions will survive termination or expiration of this License Agreement: Sections 1, 3.2, 3.5(b)(iv), 6, 9, 10.6, 11.5, 11.6 and 12. Termination or expiration of this License Agreement will not relieve the Parties of any liability or obligation which accrued hereunder prior to the effective date of such termination or expiration nor preclude either Party from pursuing all rights and remedies it may have hereunder or at law or in equity with respect to any breach of this License Agreement nor prejudice either Party's right to obtain performance of any obligation. All other rights and obligations will terminate upon expiration of this License Agreement.

12. General Provisions.

12.1 Dispute Resolution.

- (a) Disputes. Disputes arising under or in connection with this License Agreement will be resolved pursuant to this Section 12.1; provided, however, that in the event a dispute cannot be resolved without an adjudication of the rights or obligations of a Third Party (other than any Moderna Indemnitees or Acuitas Indemnitees identified in Section 10.6), the dispute procedures set forth Sections 12.1(c) and 12.1(c) will be inapplicable as to such dispute.
- (b) Dispute Escalation. In the event of a dispute between the Parties, the Parties will first attempt in good faith to resolve such dispute by negotiation and consultation between themselves. In the event that such dispute is not resolved on an informal basis within days, any Party may, by written notice to the other, have such dispute referred to each Party's who will attempt in good faith to resolve such dispute by negotiation and consultation for a day period following receipt of such written notice
- able to resolve such dispute as set forth above, the will together elect whether to submit the dispute to moderation, litigation or arbitration. In the absence of such an agreement, either party may elect to initiate litigation.
- (d) Injunctive Relief. Notwithstanding the dispute resolution procedures set forth in this Section 12.1, in the event of an actual or threatened breach hereunder, the aggrieved Party may seek equitable relief (including restraining orders, specific performance or other injunctive relief) in any court or other forum, without first submitting to any dispute resolution procedures hereunder.
- (e) Tolling. The Parties agree that all applicable statutes of limitation and time-based defenses (such as estoppel and laches) will be tolled while the dispute resolution procedures set forth in this Section 12.1 are pending, and the Parties will cooperate in taking all actions reasonably necessary to achieve such a result.
 - (f) Prevailing Party. The prevailing Party in any arbitration under Section 12.1(c) or

any other suit related to this License Agreement will be entitled to recover from the losing Party all out-of-pocket fees, costs and expenses (including those of attorneys, professionals and accountants and all those arising from appeals and investigations) incurred by the prevailing Party in connection with such arbitration or suit.

- Parties hereunder will be cumulative and in addition to all other rights and remedies provided hereunder or available by agreement, at Law or otherwise. Each Party acknowledges and agrees that breach of any of the terms or conditions of this License Agreement may cause irreparable harm and damage to the other and that such damage may not be ascertainable in money damages and that as a result thereof the non-breaching Party may be entitled to seek from a court equitable or injunctive relief restraining any breach or future violation of the terms contained herein by the breaching Party without the necessity of proving actual damages or posting bond. Such right to equitable relief is in addition to whatever remedies either Party may be entitled to as a matter of Law or equity, including money damages.
- 12.3 Relationship of Parties. Nothing in this License Agreement is intended or will be deemed to constitute a partnership, agency, employer-employee or joint venture relationship between the Parties. No Party will incur any debts or make any commitments for the other, except to the extent, if at all, specifically provided therein. Except as may be required by the Applicable In-Licenses, there are no express or implied third party beneficiaries hereunder (except for Moderna Indemnitees and Acuitas Indemnitees for purposes of Section 10.6). For clarity, Moderna does not grant to Acuitas any rights or licensed under this License Agreement to any Moderna technology or intellectual property rights.
- 12.4 <u>Compliance with Law</u>. Each Party will perform or cause to be performed any and all of its obligations or the exercise of any and all of its rights hereunder in good scientific manner and in compliance with all applicable Law.
- 12.5 <u>Governing Law</u>. This License Agreement will be governed by and construed in accordance with the Laws of the State of New York, without respect to its conflict of Laws rules, provided that any dispute relating to the scope, validity, enforceability or infringement of any Patents or Know-How will be governed by, and construed and enforced in accordance with, the substantive Laws of the jurisdiction in which such Patents or Know-How apply.
- 12.6 <u>Counterparts: Facsimiles</u>. This License Agreement may be executed in one or more counterparts, each of which will be deemed an original, and all of which together will be deemed to be one and the same instrument. Facsimile or PDF execution and delivery of this License Agreement by either Party will constitute a legal, valid and binding execution and delivery of this License Agreement by such Party
- 12.7 <u>Headings</u>. All headings in this License Agreement are for convenience only and will not affect the meaning of any provision hereof.
- 12.8 <u>Waiver of Rule of Construction</u>. Each Party has had the opportunity to consult with counsel in connection with the review, drafting and negotiation of this License Agreement. Accordingly, the rule of construction that any ambiguity in this License Agreement will be construed against the drafting party will not apply.
- 12.9 <u>Interpretation</u>. Whenever any provision of this License Agreement uses the term "including" (or "includes"), such term will be deemed to mean "including without limitation"

(or "includes without limitations"). "Herein," "hereby," "hereunder," "hereof" and other equivalent words refer to this License Agreement as an entirety and not solely to the particular portion of this License Agreement in which any such word is used. All definitions set forth herein will be deemed applicable whether the words defined are used herein in the singular or the plural. Unless otherwise provided, all references to Sections and Exhibits in this License Agreement are to Sections and Exhibits of this License Agreement. References to any Sections include Sections and subsections that are part of the related Section (e.g., a section numbered "Section 2.1" would be part of "Section 2" and references to "Section 2" would also refer to material contained in the subsection described as "Section 2.1(a).")

- 12.10 <u>Binding Effect</u>. This License Agreement will inure to the benefit of and be binding upon the Parties, their Affiliates, and their respective lawful successors and assigns.
- 12.11 <u>Assignment</u>. This License Agreement may not be assigned by either Party, nor may either Party delegate its obligations or otherwise transfer licenses or other rights created by this License Agreement, except as expressly permitted hereunder or otherwise without the prior written consent of the other Party, which consent will not be unreasonably withheld; provided that either Party may assign this License Agreement to an Affiliate or to its successor in connection with sale of all or substantially all of its assets or business or that portion of its business pertaining to the subject matter of this License Agreement (whether by merger, consolidation or otherwise).
- 12.12 <u>Notices</u>. All notices, requests, demands and other communications required or permitted to be given pursuant to this License Agreement will be in writing and will be deemed to have been duly given upon the date of receipt if delivered by hand, recognized international overnight courier, confirmed facsimile transmission, or registered or certified mail, return receipt requested, postage prepaid to the following addresses or facsimile numbers:

If to Moderna: ModernaTX, Inc.

200 Technology Square Cambridge, MA 02139 Attention:

With a copy to: ModernaTX, Inc.

320 Bent Street

Cambridge, MA 02139

Attention:

If to Acuitas: Acuitas Therapeutics Inc.

2714 West 31rst Avenue

Vancouver, B.C. Canada V6L 2A1

Attention:

With a copy to: McCarthy Tetrault LLP

Suite 1300 777 Dunsmuir Street

Vancouver, B.C. Canada V6B IN3

Attention:

Either Party may change its designated address and facsimile number by notice to the other Party in the manner provided in this Section 12.12.

- 12.13 Amendment and Waiver. This License Agreement may be amended, supplemented, or otherwise modified only by means of a written instrument signed by both Parties; provided that any unilateral undertaking or waiver made by one Party in favor of the other will be enforceable if undertaken in a writing signed by the Party to be charged with the undertaking or waiver. Any waiver of any rights or failure to act in a specific instance will relate only to such instance and will not be construed as an agreement to waive any rights or fail to act in any other instance, whether or not similar.
- 12.14 <u>Severability</u>. In the event that any provision of this License Agreement will, for any reason, be held to be invalid or unenforceable in any respect, such invalidity or unenforceability will not affect any other provision hereof, and the Parties will negotiate in good faith to modify the License Agreement to preserve (to the extent possible) their original intent.
- 12.15 <u>Entire License Agreement</u>. This License Agreement together with the Development and Option Agreement any other License Agreements entered into during the Term are the sole agreement with respect to the subject matter and supersedes all other agreements and understandings between the Parties with respect to same.
- 12.16 Force Majeure. Neither Acuitas nor Moderna will be liable for failure of or delay in performing obligations set forth in this License Agreement (other than any obligation to pay monies when due), and neither will be deemed in breach of such obligations, if such failure or delay is due to natural disasters or any causes reasonably beyond the control of Acuitas or Moderna; provided that the Party affected will promptly notify the other of the force majeure condition and will exert reasonable efforts to eliminate, cure or overcome any such causes and to resume performance of its obligations as soon as possible.

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WITNESS WHEREOF, the Parties have caused this License Agreement to be executed by their respective duly authorized officers as of the License Agreement Effective Date.

ACUITAS THERAPHUTICS INC.

Ву:	
Name:	
Title:	
Date:	OCTOBER 15th 2016
Model	RNATX, INC.
Ву:	(Signature)
Name:	
Title:	

WIINESS WHEREOF, the Parties have caused this License Agreement to be executed by their respective duly authorized officers as of the License Agreement Effective Date.

Ву:	(Signature)
Name:	
Title:	

ACUITAS THERAPEUTICS INC.

MODERNATX, INC.

Ву:												
Name:												
Title:									 	 	 	
Date:	**********	,	۵	L	11	_	***************************************	6	 	 	 00000000	

<u>Appendix A</u> Licensed Target

"Licensed Target"



Appendix B Applicable In-Licenses

Appendix C

Certain Patents within the Licensed Technology as of the License Agreement Effective Date

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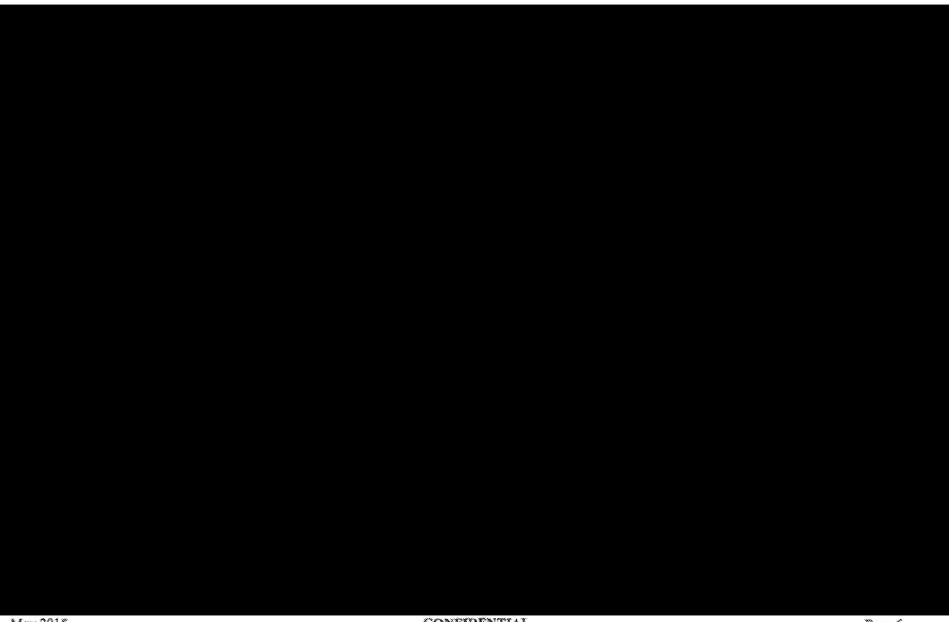


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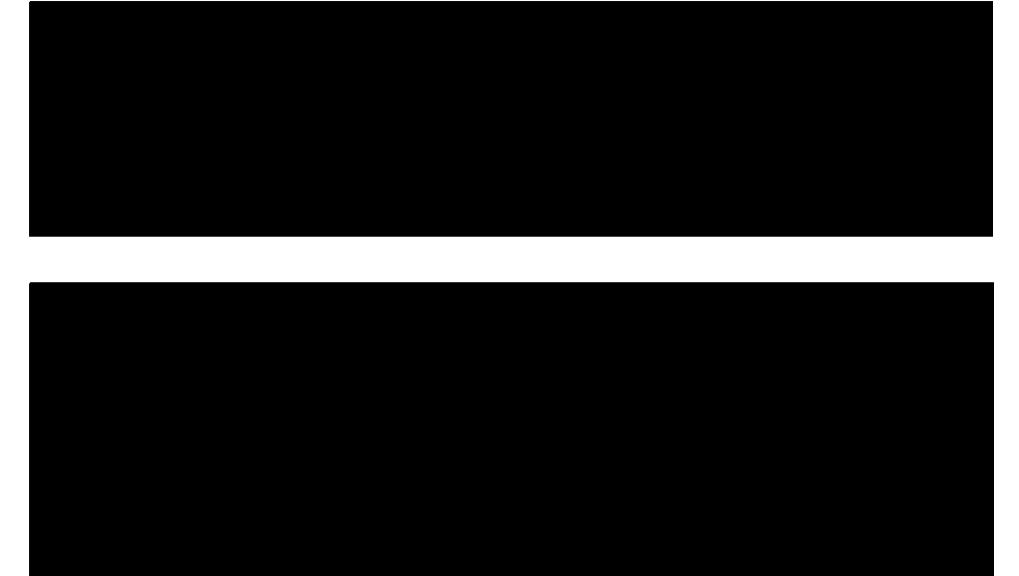
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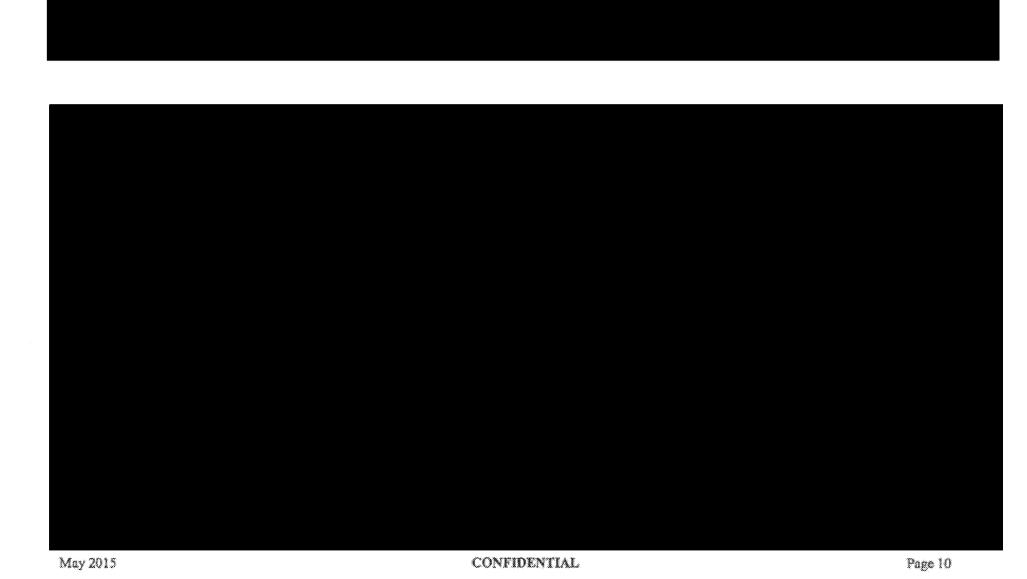
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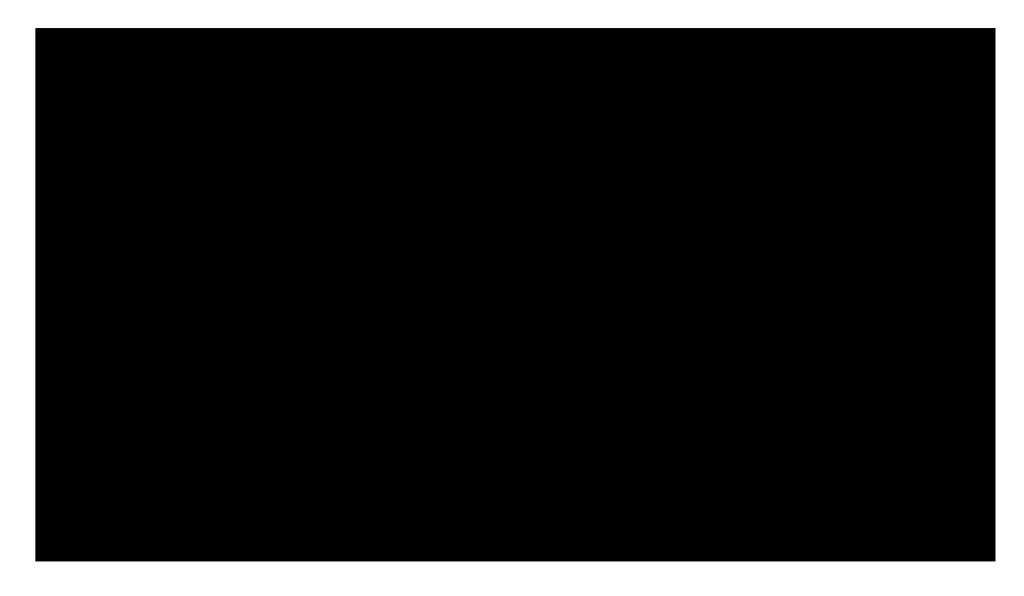


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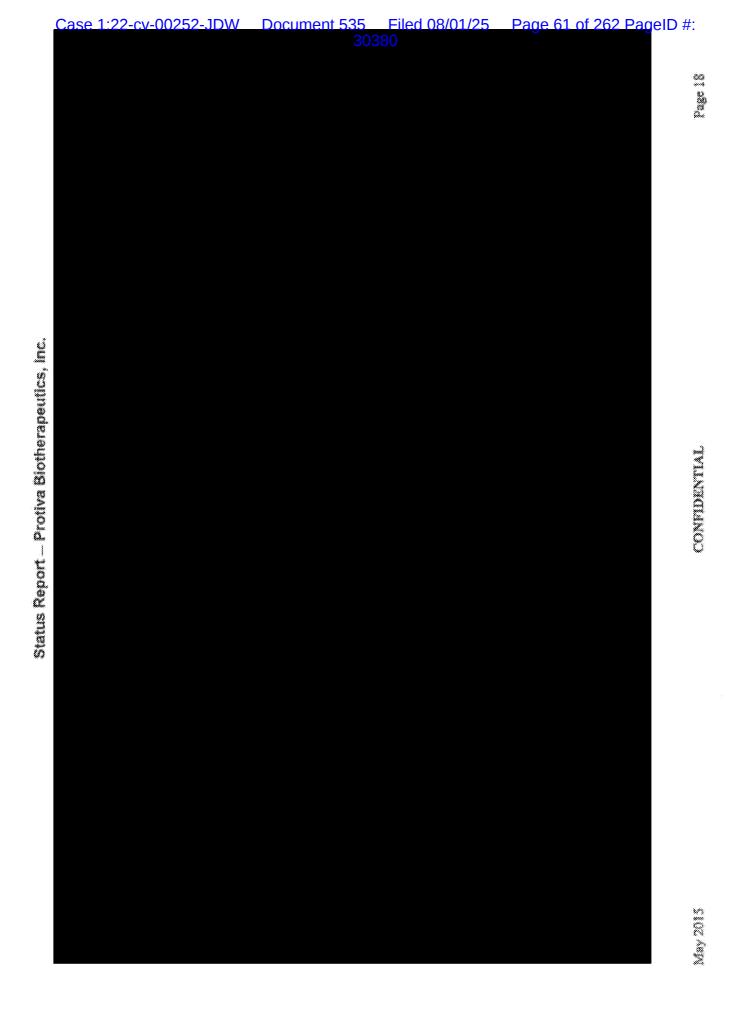


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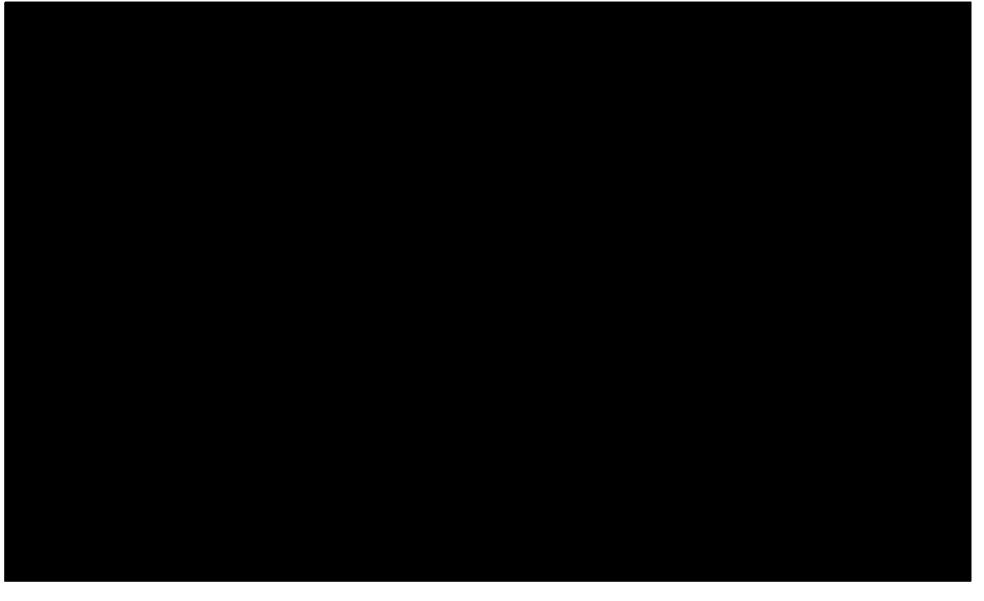
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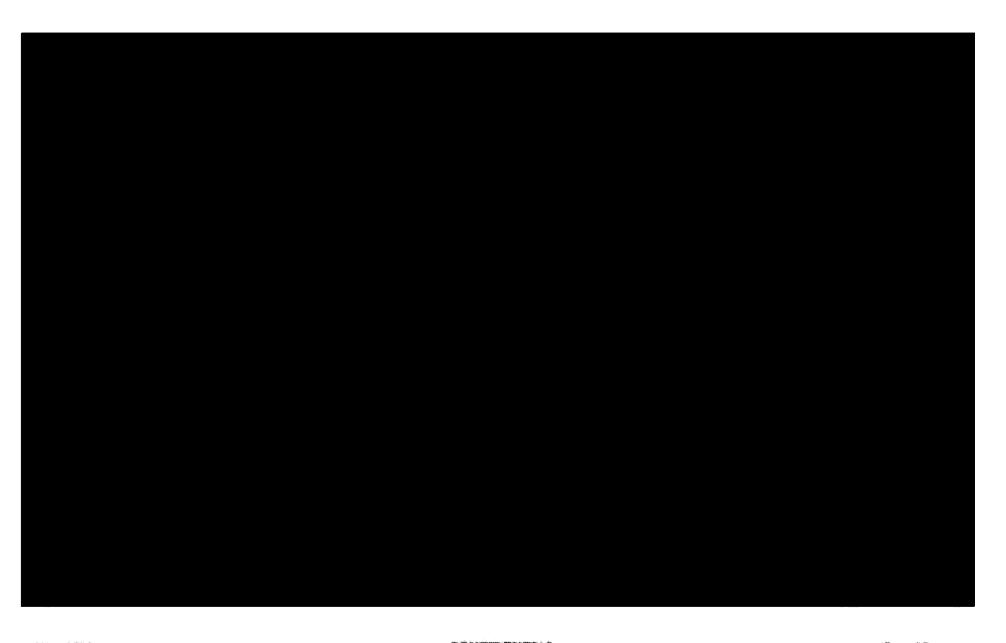


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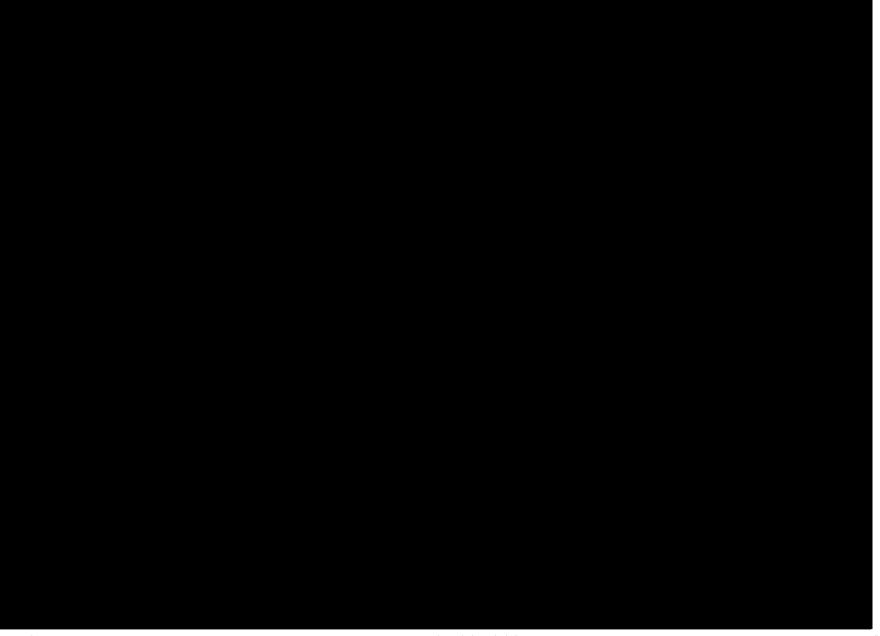
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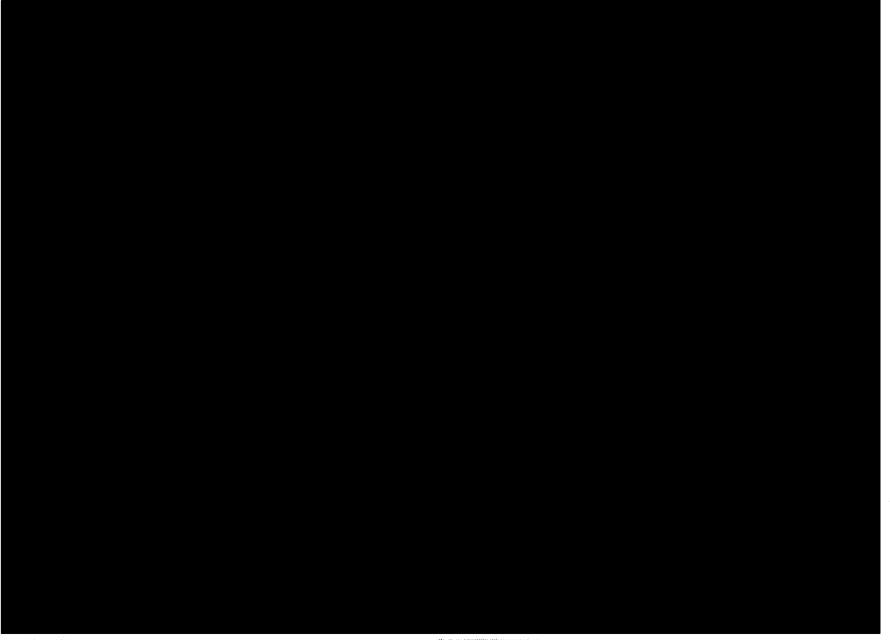
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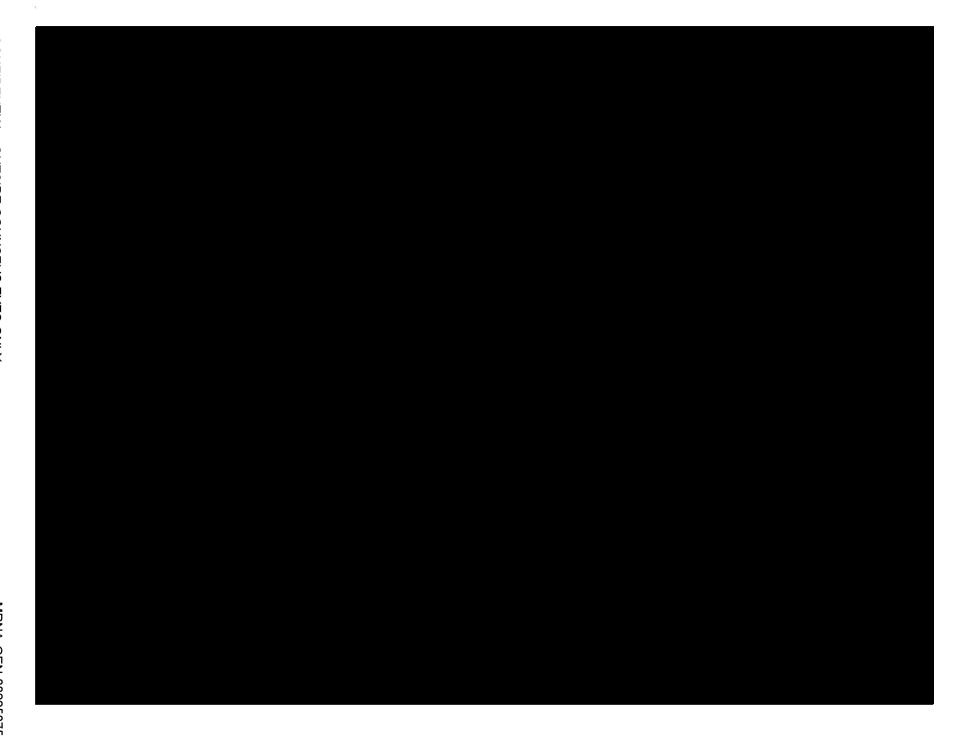


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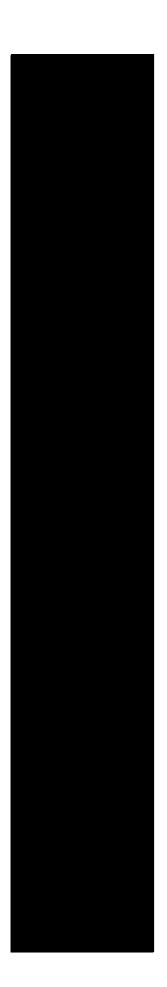
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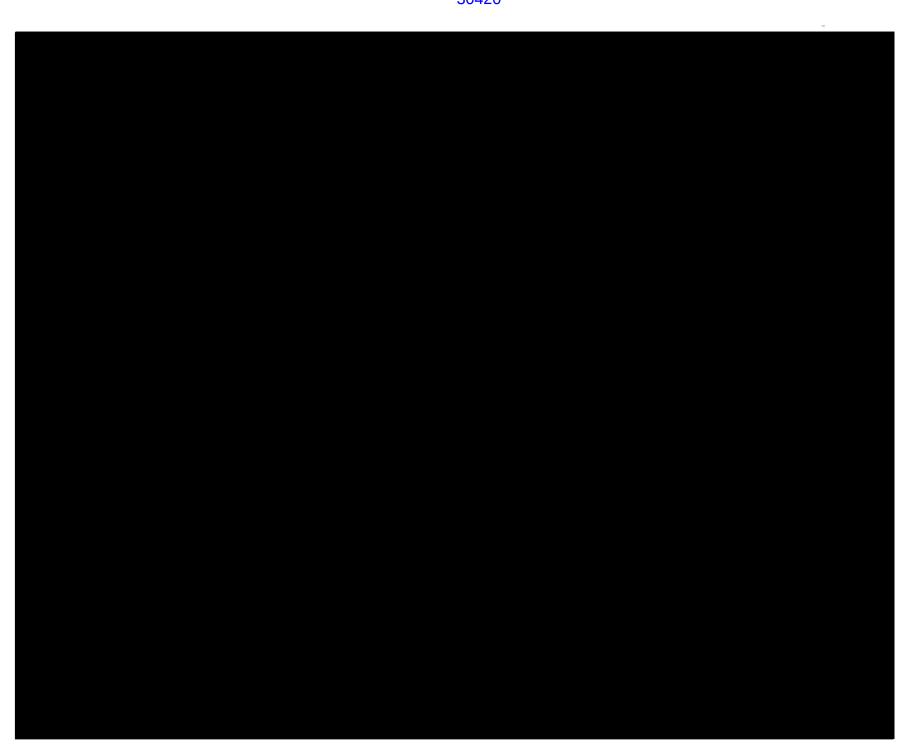


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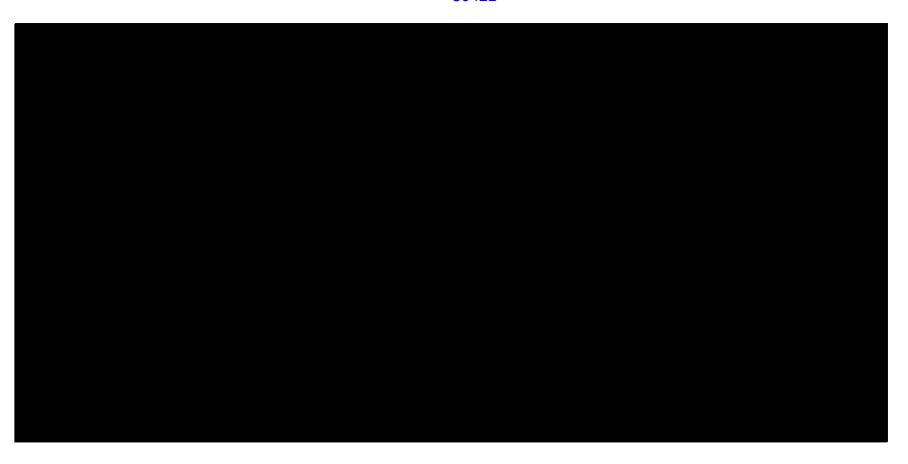


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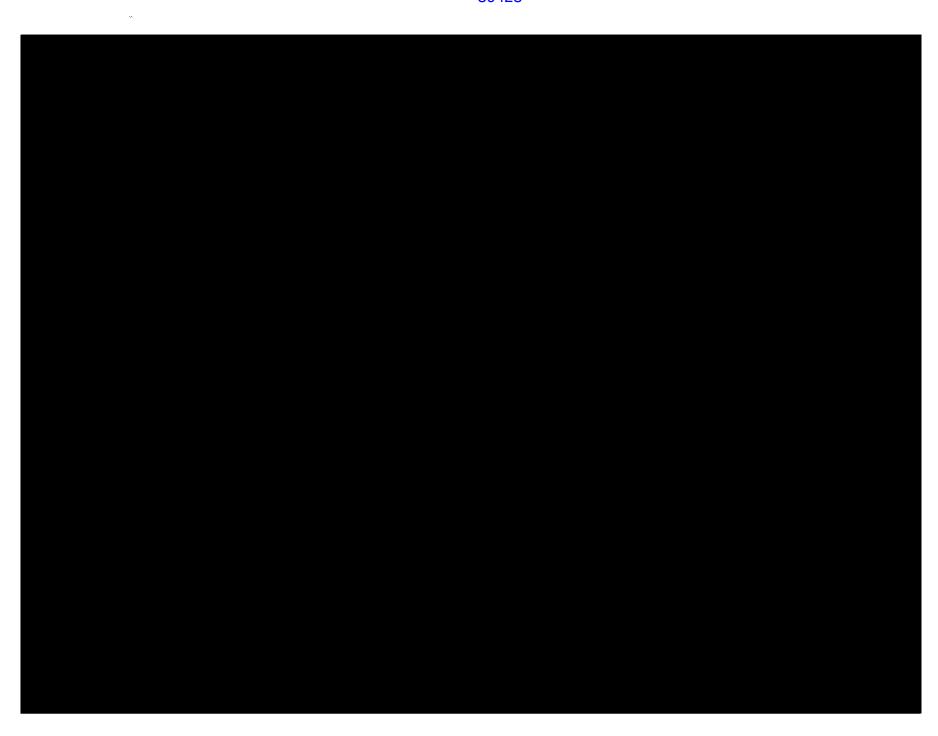




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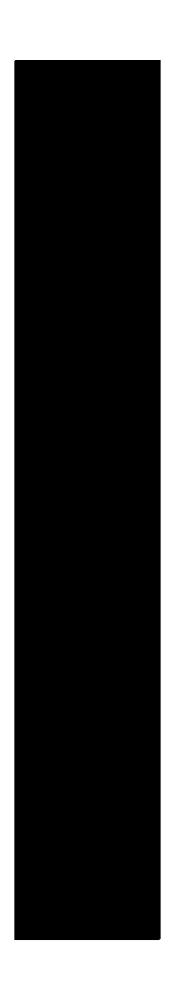
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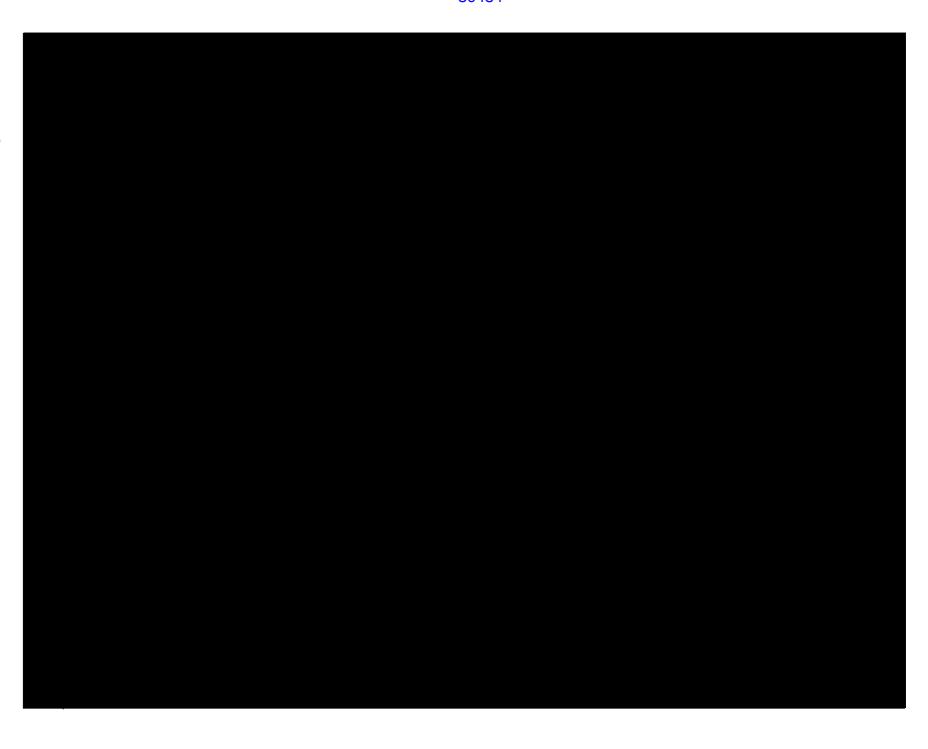
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Schedule 10.2

Exceptions to Acuitas' Representations and Warranties in Section 10.2



EXHIBIT 24

Non-Exclusive License Agreement

by and between

Acuitas Therapeutics Inc.

and

Moderna Therapeutics, Inc.

August 19, 2016

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List of Appendices

Appendix A Licensed Target

Appendix B Applicable In-Licenses

Appendix C Certain Patents within the Licensed Technology

as of the License Agreement Effective Date

Schedule 9.2 Exceptions to Acuitas' Representations and Warranties

Non-Exclusive License Agreement

This Non-Exclusive License Agreement (this "License Agreement"), dated as of August 19, 2016 (the "License Agreement Effective Date"), is made by and between Acuitas Therapeutics Inc., a British Columbia corporation ("Acuitas"), and Moderna Therapeutics, Inc., a Delaware Corporation ("Moderna"). Each of Acuitas and Moderna may be referred to herein as a "Party" or together as the "Parties."

WHEREAS, Acuitas has proprietary LNP Technology;

WHEREAS, Moderna has proprietary messenger RNA ("mRNA") technologies; and

WHEREAS, Acuitas and Moderna are parties to that certain Development and Option Agreement (dated July 3, 2014) (the "Development and Option Agreement") pursuant to which Moderna has an option to take a license under Licensed Technology (as defined below) with respect to certain mRNA products;

WHEREAS, pursuant to the terms of the Development and Option Agreement, Moderna has exercised an option with respect to a Reserved Target and the Parties are now entering into a non-exclusive licensing arrangement whereby Moderna will have a non-exclusive license under the Licensed Technology to develop and commercialize Licensed Products, all on the terms and conditions set forth here.

NOW, THEREFORE, in consideration of the mutual covenants contained herein, and for other good and valuable consideration, the amount and sufficiency of which are hereby acknowledged, the Parties hereby agree as follows:

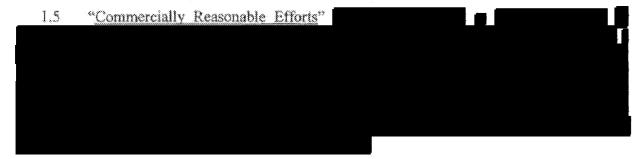
I. Definitions.

The following terms and their correlatives will have the meanings set forth below. Capitalized terms used, but not defined, herein will have the meanings ascribed to such terms in the Development and Option Agreement.

- 1.1 "Acuitas Milestone Product" means:
- 1.2 "Applicable In-Licenses" means all LNP in-Licenses that Moderna has elected to list on Appendix B as of the License Agreement Effective Date, plus any other LNP In-Licenses that Moderna has elects to include as an Applicable In-License pursuant to Section 4.1.
- 1.3 "Combination Product" means a Licensed Product that includes at least one additional active ingredient other than an mRNA Construct. Drug delivery vehicles, adjuvants, and excipients shall not be deemed to be "active ingredients", except in the case where such delivery vehicle, adjuvant, or excipient is recognized as an active ingredient in accordance with 21 C.F.R. 210.3(b)(7), provided however,
- 1.4 "Commercialization" means any and all activities directed to the Manufacturing, marketing, detailing, promotion and securing of reimbursement of a product after Regulatory Approval has been obtained (including making, having made, using, importing, selling and

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offering for sale such product), and will include post-approval clinical studies, post-launch marketing, promoting, detailing, marketing research, distributing, customer service, administering and commercially selling such product, importing, exporting or transporting such product for commercial sale, and all regulatory compliance with respect to the foregoing.



- 1.6 "Contract Year" means the period beginning on the License Agreement Effective Date and ending on the first anniversary of the License Agreement Effective Date, and each consecutive twelve (12) month period thereafter during the Term.
- 1.7 "Control" or "Controlled" means, with respect to any Know-How or Patent, the possession (whether by ownership or license, other than by a license or sublicense granted pursuant to this License Agreement) by a Party or its Affiliates of the ability to grant to the other Party a license or access as provided herein to such item, without violating the terms of any agreement or other arrangement with any Third Party.
- 1.8 "Covers", with reference to (a) a Patent, means that the making, using, selling, offering for sale or importing of a product or practice of a method would infringe a Valid Claim or Pending Claim of such Patent in the country in which such activity occurs, and (b) Know-How, means that the Manufacture, Development or Commercialization of a product incorporates or embodies such Know-How.
- 1.9 "Cross License Agreement" means the Cross License Agreement dated November 12, 2012 by and between Acuitas and Tekmira Pharmaceuticals Corporation (on behalf of itself and its wholly owned Affiliate Protiva Biotherapeutics Inc.) ("Tekmira").
- 1.10 "Development" means preclinical and clinical drug research and development activities, including: test method development and stability testing, toxicology, formulation, process development, qualification and validation, Manufacture scale-up, development-stage Manufacturing, quality assurance/quality control, clinical studies, statistical analysis and report writing, the preparation and submission of applications for Regulatory Approval, regulatory affairs with respect to the foregoing and all other activities necessary or useful or otherwise requested or required by a Regulatory Authority as a condition or in support of obtaining or maintaining a Regulatory Approval.
 - 1.11 "Field of Use" means all fields.
- 1.12 "First Commercial Sale" means the first sale for use or consumption of any Licensed Product in a country after all required Regulatory Approvals for commercial sale of such Licensed Product have been obtained in such country.
- 1.13 "Generic Product" means, with respect to a Licensed Product in a given country, any generic or biosimilar product sold by a Third Party not licensed or otherwise authorized by or on

behalf of Moderna or any of its Affiliates or Sublicensees (a) that is approved for administration to humans under 351(k) of the PHSA referencing Licensee's Regulatory Filings; or (b) foreign equivalents that have received equivalent Regulatory Approval from the applicable Regulatory Authority by referencing Acuitas' Regulatory Filings (and data therein) of such Licensed Product. Notwithstanding anything to the contrary set forth above, in no event will a product sold by or under authority of Tekmira pursuant to the Cross License Agreement be a "Generic Product" for the purposes of this.

- 1.14 "In-License Payments" means any amounts paid or payable by Acuitas or its Affiliates under any Applicable In-License that arise solely as a result of the grant of a sublicense thereunder to Moderna and its Affiliates and Sublicensees that are royalties on sales of Licensed Products or milestone payments achieved with respect to License Products. For the avoidance of doubt, "In-License Payments" shall include only royalties and milestone payments payable under the Applicable In-License and shall not include any annual maintenance fees, license fees, payments resulting from Acuitas' breach of an Applicable In-License or any other payment thereunder.
- 1.15 "Know-How" means all commercial, technical, scientific and other know-how and information, trade secrets, knowledge, technology, methods, processes, practices, formulae, instructions, skills, techniques, procedures, experiences, ideas, technical assistance, designs, drawings, assembly procedures, computer programs, specifications, data and results (including biological, chemical, pharmacological, toxicological, pharmaceutical, physical and analytical, preclinical, clinical, safety, manufacturing and quality control data and know-how, including study designs and protocols), in all cases, (a) to the extent Confidential Information of Acuitas, (b) whether or not patentable, and (c) provided by Acuitas to Moderna pursuant to the Development and Option Agreement.
- 1.16 "Licensed Product" means any product (a) that includes one (1) or more mRNA Constructs coding for the Licensed Target and (b) the Manufacture, use, sale, offer for sale or importation of which in or into a particular country is Covered by the Licensed Technology, as determined on a product-by-product and country-by-country basis.
- 1.17 "Licensed Proprietary Technology" means all Know-How, Patents and Materials and that (a) Cover LNP Technology (including the manufacture or use thereof), and (b) are owned by Acuitas or any of its Affiliates at the relevant point in time, and (c) that may be necessary or useful to Develop and Commercialize Licensed Products.
 - 1.18 "Licensed Target" means the Target identified on Appendix A hereto.
- 1.19 "<u>Licensed Technology</u>" means the Licensed Proprietary Technology and Licensed Third Party Technology.
- 1.20 "Licensed Third Party Technology" means any and all Know-How, Patents and Materials that (a) Cover LNP Technology (including the manufacture or use thereof), and (b) that are in-licensed by Acuitas or its Affiliates pursuant to the Applicable In-Licenses (including any extensions or expansions of the scope thereof), and (c) are Controlled at the applicable time by Acuitas or any of its Affiliates and (d) that may be necessary or useful to Develop and Commercialize Licensed Products.
- 1.21 "LNP In-Licenses" means all agreements entered into prior to the License Agreement Effective Date or at any time during the Term between Acuitas or its Affiliates and a Third Party

pursuant to which Acuitas or its Affiliates is granted a license or other rights to LNP Technology that may be necessary or useful to Develop and Commercialize Licensed Products.

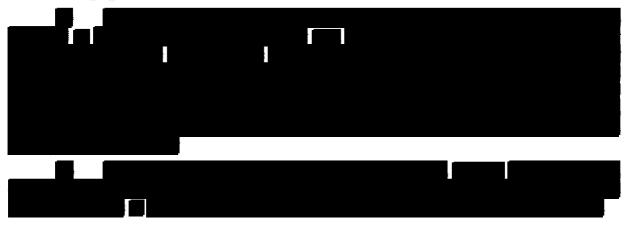


1.23 "Manufacturing" means the production, manufacture, processing, filling, finishing, packaging, labeling, shipping and holding of product or any intermediate thereof, including process development, process qualification and validation, scale-up, commercial manufacture and analytic development, product characterization, stability testing, quality assurance and quality control.



- 1.26 "Patent" means the rights and interests in and to all issued patents and pending patent applications in any country, including, without limitation, all provisional applications, substitutions, continuations, continuations-in-part, divisions, and renewals, all letters patent granted thereon, and all patents-of-addition, reissues, reexaminations and extensions or restorations by existing or future extension or restoration mechanisms, including, without limitation Supplementary Protection Certificates or the equivalent thereof.
- 1.27 "Patent Costs" means the reasonable, documented, out-of-pocket costs and expenses paid to outside legal counsel, and filing and maintenance expenses, actually and reasonably incurred by a Party in prosecuting and maintaining Patents and enforcing and defending them.
- 1.28 "Pending Claim" means, with respect to a particular country, any claim of a pending Patent application in such country that (a) has not been held revoked, unenforceable or invalid by a decision of a court or governmental agency of competent jurisdiction from which no further appeal is possible (other than to the United States Supreme Court), (b) has not been abandoned, disclaimed, denied or admitted to be invalid or unenforceable through reissue or disclaimer or otherwise in such country, and (c)
- 1.29 "Phase 1 Study" means a human clinical trial of a Licensed Product in any country, the primary purpose of which is the determination of safety and which may include the determination of pharmacokinetic and/or pharmacodynamic profiles in healthy individuals or patients.
- 1.30 "Phase 2 Study" means a human clinical trial of a Licensed Product in any country, and which is: (a) a study of dose exploration, dose response, duration of effect, kinetics or preliminary efficacy and safety study of a product in the target patient population, (b) a controlled dose-ranging clinical trial to evaluate further the efficacy and safety of such product in the target population and to define the optimal dosing regimen or (c) a clinical trial that Moderna refers to in a press release as a Phase II (or IIa or IIb) clinical trial or study.
- 1.31 "Phase 3 Study" means a human clinical trial of a Licensed Product in any country, and which is: (a) a controlled study of a product in patients of the efficacy and safety of such product which is prospectively designed to demonstrate statistically whether such product is effective and safe for use in a particular indication in a manner sufficient to obtain Regulatory Approval to market such product or (b) a clinical trial that Moderna refers to in a press release as a Phase III or registration clinical trial or pivotal study.
- 1.32 "Regulatory Approval" means, with respect to a country or extra-national territory, any and all approvals (including BLAs and MAAs), licenses, registrations or authorizations of any Regulatory Authority necessary in order to commercially distribute, sell or market a product in such country or some or all of such extra-national territory, excluding any pricing or reimbursement approvals.
- 1.33 "Regulatory Authority" means any national (e.g., the FDA), supra-national (e.g., the EMA), regional, state or local regulatory agency, department, bureau, commission, council or other governmental authority, in any jurisdiction in the world, involved in the granting of Regulatory Approval.

- 1.34 "Sublicensee" means any Third Party that is granted a sublicense as permitted by Section 3.5, either directly by Moderna or its Affiliates or indirectly by any other Sublicensee hereunder.
 - 1.35 "Target" means either:



1.36 "Territory" means worldwide.

1.37	"Valid Claim	" means,	with	respect	to a	particular	country,	any	claim	of an	issued	and
unexpired	Patent in such	country	that									

Definitions for each of the following terms are found in the body of this License Agreement as indicated below:

Defined Terms	Location
Acuitas Indemnitees	Section 10.6(a)
Competitive Infringement	Section 8.1
Indemnification Claim Notice	Section 10.6(c)
Indemnified Party	Section 10.6(c)
In-License Milestone Payments	Section 5.1
In-License Royalties	Section 5.1
Losses	Section 10.6(a)
Acuitas Milestone Event	Section 5.1
Acuitas Milestone Payment	Section 5.1
Moderna Indemnitees	Section 10.6(b)
Solely Owned IP	Section 6.1
Term	Section 11.1
Third Party Claims	Section 10.6(a)

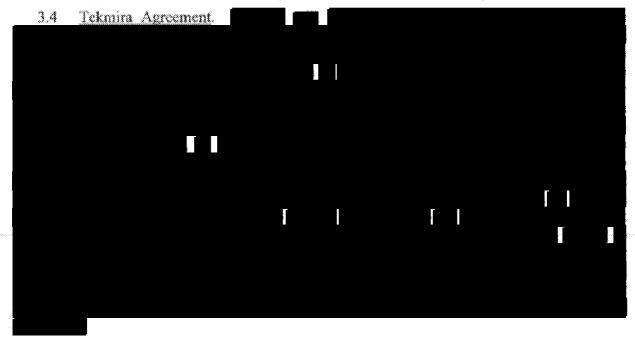
2. Development and Commercialization.

2.1 <u>Development</u>. Moderna shall have sole responsibility for, and shall bear all its costs of conducting, all Development and Commercialization of Licensed Products (including filing for and obtaining all required Regulatory Approvals). As between the Parties, all such Regulatory Approvals shall be obtained by and in the name of Moderna (or its Affiliates or Sublicensees).

License Grants.

3.1 Licenses by Acuitas.

- (a) Licensed Technology. Subject to the terms and conditions of this License Agreement, Acuitas and its Affiliates hereby grant to Moderna and its Affiliates (a) a non-exclusive, non-transferrable (other than pursuant to Section 12.11) license, with the right to sublicense only as permitted by Section 3.5(b), under the Licensed Technology, to Develop and Commercialize Licensed Products in the Field of Use in the Territory.
- 3.2 No Obligation to Provide Know-How. The Parties acknowledge and agree that neither Acuitas nor any of its Affiliates is obligated hereunder to, or will, absent prior written agreement by the Parties, transfer to Moderna or its Affiliates any Know-How or materials.
- of Patents that are added to the Licensed Technology following the Effective Date or any Patents that have been abandoned or discontinued in accordance with the terms of this License Agreement.
 Appendix C shall be automatically updated to include any such added Patents provided that, with written notice to Acuitas, Moderna may elect to exclude any particular Patents from the Licensed Technology. Following any such notice by Moderna, the applicable Patents that Moderna identifies for exclusion from this License Agreement will no longer be licensed to Moderna hereunder, and Moderna shall not have any obligations hereunder with respect to such Patent.



3.5 Sublicensing Rights.

(a) Transfer. The licenses granted in Sections 3.1 are transferable only upon a permitted assignment of this License Agreement in accordance with Section 12.11.

- (b) Moderna Sublicenses. The licenses granted in Section 3.1 may be sublicensed, in full or in part, by Moderna or its Affiliates or Sublicensees by a written agreement to Third Parties (with the right to sublicense through multiple tiers), provided, that:
- (i) Each sublicense will be in writing and on terms consistent with and subject to the terms of this Agreement,
- (ii) Moderna will provide Acuitas with a copy of any sublicense agreement with a Sublicensee within of execution thereof, which sublicense agreement may be redacted as necessary to protect commercially sensitive information and shall be treated as Moderna Confidential Information hereunder,
- (iii) Moderna will be responsible for any and all obligations of such Sublicensee as if such Sublicensee were "Moderna" hereunder; and
- (iv) Any sublicense granted by Moderna to any rights licensed to it hereunder shall terminate immediately upon the termination of the license from Acuitas to Moderna and its Affiliates with respect to such rights, provided that such sublicensed rights shall not terminate if, as of the effective date of such termination pursuant to Sections 11.2, 11.3(a) or 11.4, a Sublicensee is not in material default of its obligations under its sublicense agreement, and within days of such termination the Sublicensee agrees in writing to be bound directly to Acuitas under a license agreement substantially similar to this License Agreement with respect to the rights sublicensed hereunder, substituting such Sublicensee for Moderna.
- 3.6 <u>License Limitations</u>. No licenses or other rights are granted by Acuitas hereunder to use any trademark, trade name, trade dress or service mark owned or otherwise Controlled by Acuitas or any of its Affiliates. All licenses and other rights are or shall be granted only as expressly provided in this License Agreement, and no other licenses or other rights is or shall be created or granted by either Party hereunder by implication, estoppel or otherwise.

4. Applicable In-Licenses.

Applicable In-Licenses. The Applicable In-Licenses as of the License Agreement 4.1 Effective Date are listed in Appendix B. If during the Term Acuitas or its Affiliates enters into any Third Party In-License pursuant to which Acuitas or its Affiliates in-licenses any Patents or Know-How Covering LNP Technology that is Controlled by Acuitas or its Affiliates, Acuitas will notify Moderna of same and provide Moderna promptly with a copy of such Third Party In-License (which may be redacted as necessary to protect commercially sensitive information of Acuitas that is not relevant to the grant of a sublicense to Moderna). Moderna shall have the option of including any such Third Party In-License within the scope of this License Agreement by providing Acuitas with notice of same, provided that (a) such notice is provided to Acuitas within of Moderna's receipt of notice from Acuitas, or (b) if such notice is provided to Acuitas later than of Moderna's receipt of notice from Acuitas, the LNP Technology that is in-licensed by Acuitas or its Affiliates pursuant to the Third Party In-License is still Controlled by Acuitas or its Affiliates for the purposes of granting a sublicense to Moderna hereunder. Appendix B will automatically be updated to include such Third Party In-License added in accordance with subsections (a) or (b) above and the provisions of this License Agreement applicable to Applicable In-Licenses, including Section 5.1, will apply with respect to such Third Party In-License.

4.2 <u>Maintenance of Applicable In-Licenses</u>. Acuitas (a) will duly perform and observe all of its obligations under the Applicable In-Licenses in all material respects (and in all respects if the failure to do so would give rise to a right of termination on the part of the licensor) and

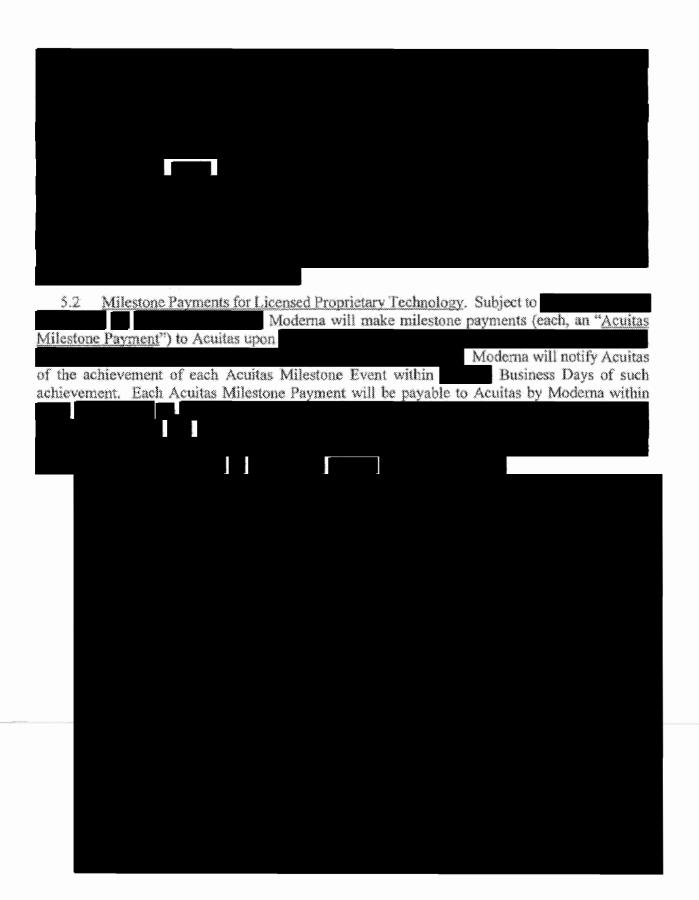


4.3 <u>Applicable In-License Requirements</u>. Moderna will abide, and will cause all its Affiliates and applicable Sublicensees to abide, by all requirements of each Applicable In-License in all material respects, to the extent applicable to sublicensees thereunder and to the extent disclosed by Acuitas to Moderna

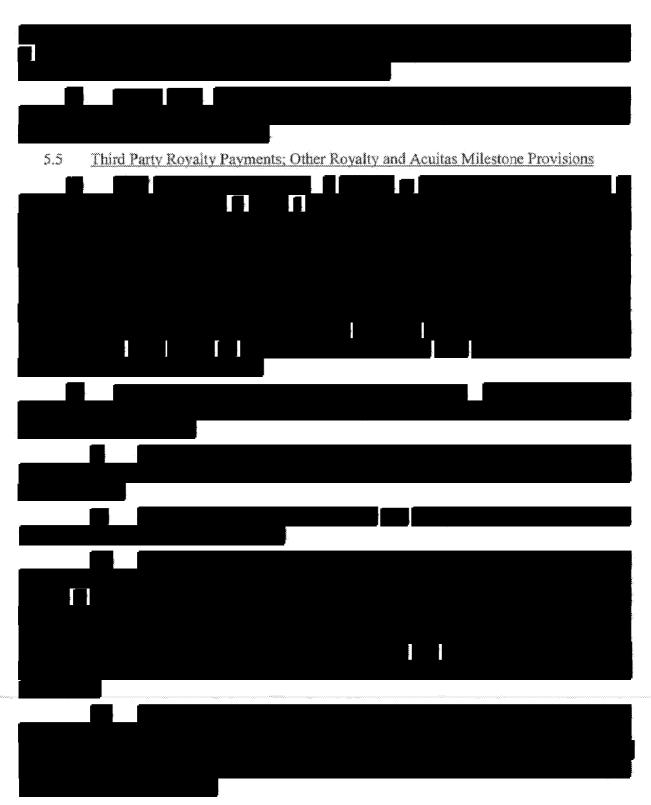


5. Payments and Royalties.









5.6 Payment Terms.

(a) Manner of Payment. All payments to be made by Moderna hereunder will be made in U.S. dollars by wire transfer to such bank account as Acuitas may designate.

(b) Records and Audits. Moderna shall keep, and shall cause each of its Affiliates and
Sublicensees, as applicable, to keep adequate books and records of accounting for the purpose of
calculating all royalties payable to Acuitas hereunder. For the next following the
end of the calendar year to which each shall pertain, such books and records of accounting
(including those of Moderna's Affiliates and Sublicensees, as applicable) shall be kept at each of
their principal place of business and shall be open for inspection at reasonable times and upon
reasonable notice by an independent certified accountant selected by Acuitas, and which is
reasonably acceptable to Moderna, for the sole purpose of inspecting the royalties due to Acuitas
under this License Agreement. In no event shall such inspections be conducted hereunder more
frequently than once Such accountant must have executed and
delivered to Moderna and its Affiliates or Sublicensees, as applicable, a confidentiality agreement
as reasonably requested by Moderna, which shall include provisions limiting such accountant's
disclosure to Acuitas to only the results and basis for such results of such inspection. The results
of such inspection, if any, shall be binding on both Parties. Any underpayments shall be paid by
Moderna within of notification of the results of such inspection. Any
overpayments shall be fully creditable against amounts payable in subsequent payment periods.
Acuitas shall pay for such inspections, except that in the event there is any upward adjustment in
aggregate royalties payable for any calendar year shown by such inspection of more than
of the amount paid, Moderna shall reimburse Acuitas for any reasonable out-of-
pocket costs of such accountant.
(c) Reports and Royalty Payments. For as long as royalties are due under Section 5.1
or 5.4, Moderna shall furnish to Acuitas a written report for each Calendar Quarter, showing the
amount of Net Sales of Licensed Products and royalty due for such Calendar Quarter. Reports
shall be provided within growing of the end of the quarter for Net Sales generated by
Moderna and its Affiliates, and within of the end of the quarter for Net Sales
garagated by Sublicances. Payalty narments for each Calendar Operter shall be due at the same

generated by Subjectsess. Koyaity payments for each Calendar Quarter shall time as such written report for the Calendar Quarter. :

All such reports shall be

treated as Confidential Information of Moderna but may be disclosed by Acuitas as required under the Applicable In-Licenses.

Currency Exchange. With respect to Net Sales invoiced in U.S. dollars, the Net Sales and the amounts due to Acuitas hereunder will be expressed in U.S. dollars. With respect to Net Sales invoiced in a currency other than U.S. dollars, payments will be calculated based on standard methodologies employed by Moderna or its Affiliates or Sublicensees for consolidation purposes for the Calendar Quarter for which remittance is made for royalties.

- (e) Taxes. Moderna may withhold from payments due to Acuitas amounts for payment of any withholding tax that is required by Law to be paid to any taxing authority with respect to such payments. Moderna will provide Acuitas all relevant documents and correspondence, and will also provide to Acuitas any other cooperation or assistance on a reasonable basis as may be necessary to enable Acuitas to claim exemption from such withholding taxes and to receive a refund of such withholding tax or claim a foreign tax credit. Moderna will give proper evidence from time to time as to the payment of any such tax. The Parties will cooperate with each other in seeking deductions under any double taxation or other similar treaty or agreement from time to time in force. Such cooperation may include Moderna making payments from a single source in the U.S., where possible. Apart from any such permitted withholding and those deductions expressly included in the definition of Net Sales, the amounts payable by Moderna to Acuitas hereunder will not be reduced on account of any taxes, charges, duties or other levies.
- (f) Blocked Payments. In the event that, by reason of applicable Law in any country, it becomes impossible or illegal for Moderna or its Affiliates or Sublicensees to transfer, or have transferred on its behalf, payments owed to Acuitas hereunder, Moderna will promptly notify Acuitas of the conditions preventing such transfer and such payments will be deposited in local currency in the relevant country to the credit of Acuitas in a recognized banking institution designated by Acuitas or, if none is designated by Acuitas within a period of days, in a recognized banking institution selected by Moderna or its Affiliate or Sublicensee, as the case may be, and identified in a written notice given to Acuitas.
- (g) Interest Due. If any payment due to Acuitas under this License Agreement is overdue (and is not subject to a good faith dispute), then Acuitas will pay interest thereon (before and after any judgment) at an annual rate (but with interest accruing on a daily basis) of the lesser

(h) Mutual Convenience of the Parties. The royalty and other payment obligations set forth hereunder have been agreed to by the Parties for the purpose of reflecting and advancing their mutual convenience, including the ease of calculating and paying royalties and other amounts to Acuitas.

6. Ownership and Inventorship of IP.

6.1 <u>Solely-Owned IP</u>. As between the Parties, each Party will own and retain all right, title and interest in and to any and all Know-How and Patents arising therefrom that are discovered, created, conceived, developed or reduced to practice solely by or on behalf of such Party under or in connection with this License Agreement ("<u>Solely Owned IP</u>"). Subject to the licenses hereunder and the other terms and conditions of this License Agreement, each Party will be solely responsible for the Prosecution and Maintenance, and the enforcement and defense, of any Patents within its Solely Owned IP.

7. Patent Prosecution and Maintenance.

7.1 <u>Generally</u>. As between the Parties, Acuitas will have the sole right to prosecute and maintain Patents within the Licensed Proprietary Technology. Acuitas will regularly provide Moderna with copies of all applications for Patents within the Licensed Proprietary Technology, and all other material submissions and correspondence with any Patent authorities regarding such

Patents, in sufficient time to allow for review and comment by Moderna. In addition, Acuitas will provide Moderna and its counsel with an opportunity to consult with Acuitas and its counsel regarding prosecution and maintenance of any such Patents, and Acuitas will consider in good faith all reasonable comments timely made by Moderna and its counsel.

- 7.2 Election Not to Prosecute or Maintain or Pav Patent Costs. If Acuitas elects not (i) to prosecute or maintain any Patents within the Licensed Proprietary Technology in any particular country before the applicable filing deadline or continue such activities once filed in a particular country, or (ii) to pay the Patent Costs associated with prosecution or maintenance of any Patents within the Licensed Proprietary Technology then in each such case Acuitas will so notify Moderna, promptly in writing and in good time to enable Acuitas to meet any deadlines by which an action must be taken to preserve such Patent in such country, if Moderna so requests. Upon receipt of each such notice by Acuitas, Moderna will have the right, but not the obligation, to notify Acuitas in writing on a timely basis that Acuitas should continue the prosecution or maintenance of such Patent, at Moderna's expense and thereafter,
- 7.3 Third Party Rights. To the extent that a Third Party licensor of Acuitas has provided Acuitas or its Affiliates with rights to prosecute or maintain and/or defend any Patent within the Licensed Third Party Technology licensed to Moderna hereunder, or to review or comment with respect to any such maintenance or prosecution activities, Acuitas will provide Moderna with the opportunity to consult with Acuitas and its counsel in connection therewith and will consider in good faith Moderna's comments to the extent permitted under such Applicable In-License.
- 7.4 Patent Extensions. If any election for Patent term restoration or extension, supplemental protection certificate or any of their equivalents may be made with respect to any Patent within the Licensed Proprietary Technology, after consultation with Moderna, the Parties will discuss and seek to reach mutual agreement whether or not to take such action. If the Parties are not able to reach mutual agreement, (a) Moderna will have the sole right to make the final decision whether or not to seek such Patent term restoration or extension, supplemental protection certificate or any of their equivalents with respect to Patents within the Licensed Proprietary Technology that cover Licensed Product and no product licensed to any other licensee of Acuitas or Commercialized by Acuitas, and (b) Acuitas will have the sole right to make the final decision whether or not to seek such Patent term restoration or extension, supplemental protection certificate or any of their equivalents with respect to all other Patents within the Licensed Proprietary Technology that claim Licensed Products and other products licensed by Acuitas or Commercialized by Acuitas.
- 7.5 Regulatory Exclusivity Periods. With respect to any Patent listings required for any regulatory exclusivity periods for Licensed Products the Parties will mutually agree on which Patents within the Licensed Technology to list, provided that if the Parties are not able to agree, Moderna will have the right to make the final decision with respect to Patents within the Licensed Proprietary Technology that cover Licensed Product and no product licensed to any other licensee of Acuitas or Commercialized by Acuitas, and provided further that the exercise of such right by Moderna will not increase or otherwise change the rights or obligations of the Parties hereunder.
- 7.6 <u>Cooperation</u>. Each Party will reasonably cooperate with the other Party in the prosecution and maintenance of Patents within the Licensed Technology. Such cooperation

includes promptly executing all documents, or requiring inventors, subcontractors, employees and consultants and agents of Moderna and Acuitas and their respective Affiliates and Sublicensees to execute all documents, as reasonable and appropriate so as to enable the prosecution and maintenance of any such Patents in any country.

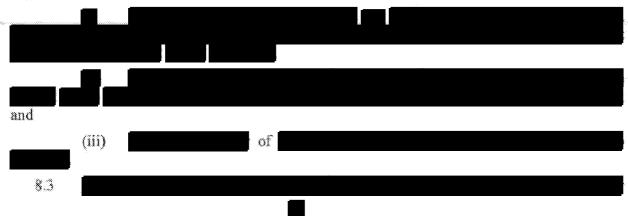
8. Patent Enforcement and Defense.

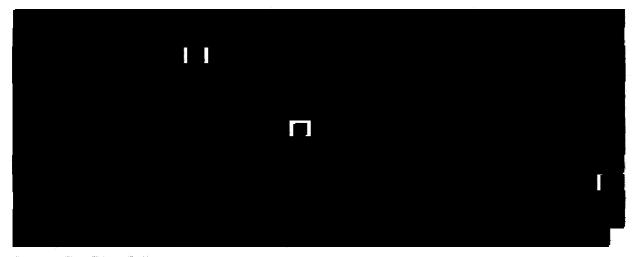
8.1 Notice. Each Party will promptly notify, in writing, the other Party upon learning of any actual or suspected Competitive Infringement of any Patents within the Licensed Technology by a Third Party, or of any claim of invalidity, unenforceability, or non-infringement of any Patents within the Licensed Technology, and will, along with such notice, supply the other Party with any evidence in its possession pertaining thereto. For purposes of this License Agreement, "Competitive Infringement" means

8.2 Enforcement and Defense.

- (a) Patents within the Licensed Technology and Competitive Infringement.
- (i) As between the Parties, Acuitas will have the first right, but not the obligation, to seek to abate any Competitive Infringement of the Patents within the Licensed Proprietary Technology by a Third Party, or to file suit against any such Third Party for such Competitive Infringement of Acuitas-Owned Technology, and, if permitted pursuant to an Applicable In-License, Licensed Third Party Technology. If Acuitas does not take steps to abate such Competitive Infringement, or file suit to enforce the Patents within the Licensed Technology against such Third Party with respect to such Competitive Infringement, within a commercially reasonably time, Moderna will have the right (but not the obligation) to take action to enforce the Patents within the Licensed Proprietary Technology that cover Licensed Product and no product licensed to any other licensee of Acuitas or Commercialized by Acuitas against such Third Party for such Competitive Infringement. The controlling Party will pay all its Patent Costs incurred for such enforcement.
- (ii) Neither Party will exercise any of its enforcement rights under this Section 8.2(a) without first consulting with the other Party, provided that this consultation requirement will not limit either Party's rights under this Section 8.2(a).
- (b) Defense. As between the Parties, Acuitas will have the first right, but not the obligation, to defend against a declaratory judgment action or other action challenging any Patents within the Licensed Proprietary Technology, other than with respect to any action or counter claims by a Third Party in response to an enforcement action brought by Moderna alleging infringement of any Patents within the Licensed Technology, which defense will be controlled by the Party controlling such enforcement action. If Acuitas does not take steps to defend within a commercially reasonably time, or elects not to continue any such defense (in which case it will promptly provide notice thereof to Moderna), then Moderna will have the right (but not the obligation) to defend any such Patent within the Licensed Proprietary Technology that cover Licensed Product and no product licensed to any other licensee of Acuitas or Commercialized by Acuitas.
- (c) Withdrawal, Cooperation and Participation. With respect to any infringement or defensive action identified above in this Section 8.2:

- (i) If the controlling Party ceases to pursue or withdraws from such action, it will promptly notify the other Party (in good time to enable the other Party to meet any deadlines by which any action must be taken to preserve any rights in such infringement or defensive action) and such other Party may substitute itself for the withdrawing Party and proceed under the terms and conditions of this Section 8.2.
- (ii) The non-controlling Party will cooperate with the Party controlling any such action (as may be reasonably requested by the controlling Party), including (A) providing access to relevant documents and other evidence, (B) making its and its Affiliates and licensees and Sublicensees and all of their respective employees, subcontractors, consultants and agents available at reasonable business hours and for reasonable periods of time, but only to the extent relevant to such action, and (C) if necessary, by being joined as a party, subject for this clause (C) to the controlling Party agreeing to indemnify such non-controlling Party for its involvement as a named party in such action and paying those Patent Costs incurred by such Party in connection with such joinder. The Party controlling any such action will keep the other Party updated with respect to any such action, including providing copies of all documents received or filed in connection with any such action.
- (iii) Each Party will have the right to participate or otherwise be involved in any such action controlled by the other Party, in each case at the participating Party's sole cost and expense. If a Party elects to so participate or be involved, the controlling Party will provide the participating Party and its counsel with an opportunity to consult with the controlling Party and its counsel regarding the prosecution of such action (including reviewing the contents of any correspondence, legal papers or other documents related thereto), and the controlling Party will take into account reasonable requests of the participating Party regarding such enforcement or defense.
- (d) Settlement. Neither Party will settle or consent to an adverse judgment in any action described in this Section 8.2 and controlled by such Party, including any judgment which affects the scope, validity or enforcement of any Patents within the Licensed Technology involved therewith, without the prior written consent of the other Party (such consent not to be unreasonably withheld or delayed).
- (e) Damages. Unless otherwise agreed by the Parties, all monies recovered upon the final judgment or settlement of any action described in Section 8.2(a) or any action described in Section 8.2(b) controlled by Moderna will be used first to reimburse each of the Parties, for each of their out-of-pocket costs and expenses relating to the action, with the balance of any such recovery to be divided as follows:





9. Confidentiality.

- 9.1 <u>Confidential Information</u>. Each Party ("<u>Disclosing Party</u>") may disclose to the other Party ("<u>Receiving Party</u>"), and Receiving Party may acquire during the course and conduct of activities under this License Agreement, certain proprietary or confidential information of Disclosing Party in connection with this License Agreement. The term "<u>Confidential Information</u>" means (i) all Materials and (ii) all ideas and information of any kind, whether in written, oral, graphical, machine-readable or other form, whether or not marked as confidential or proprietary, which are disclosed or made available by or on behalf of the Disclosing Party to the Receiving Party, including any of the foregoing of Third Parties.
- Restrictions. During the Term and for thereafter, Receiving Party will keep all Disclosing Party's Confidential Information in confidence with the same degree of care with which Receiving Party holds its own confidential information, but in no event less than reasonable care. Receiving Party will not use Disclosing Party's Confidential Information except for in connection with the performance of its obligations and exercise of its rights under this License Agreement. Receiving Party has the right to disclose Disclosing Party's Confidential Information without Disclosing Party's prior written consent to Receiving Party's Affiliates, Approved Partners, and each of their employees, subcontractors, consultants or agents who have a need to know such Confidential Information in order to perform its obligations and exercise its rights under this License Agreement and who are required to comply with the restrictions on use and disclosure that are no less restrictive than those set forth in this Section 9.2. Receiving Party assumes responsibility for those entities and persons maintaining Disclosing Party's Confidential Information in confidence and using same only for the purposes described herein.
- Exceptions. Receiving Party's obligation of nondisclosure and the limitations upon the right to use the Disclosing Party's Confidential Information will not apply to the extent that Receiving Party can demonstrate that the Disclosing Party's Confidential Information: (i) was known to Receiving Party or any of its Affiliates prior to the time of disclosure by the Disclosing Party; (ii) is or becomes public knowledge through no fault or omission of Receiving Party or any of its Affiliates; (iii) is obtained on a non-confidential basis by Receiving Party or any of its Affiliates from a Third Party who to Receiving Party's knowledge is lawfully in possession thereof and under no obligation of confidentiality to Disclosing Party; or (iv) has been independently developed by or on behalf of Receiving Party or any of its Affiliates without the aid, application or use of Disclosing Party's Confidential Information.

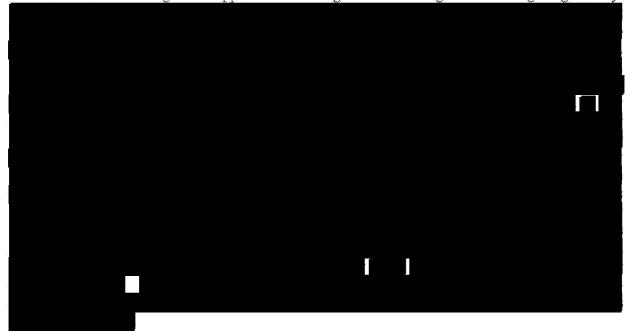
- 9.4 <u>Permitted Disclosures</u>. Receiving Party may disclose Disclosing Party's Confidential Information to the extent (and only to the extent) such disclosure is reasonably necessary in the following instances:
- (a) in order to comply with applicable Law (including any securities Law or regulation or the rules of a securities exchange) or with a legal or administrative proceeding;
- (b) in connection with prosecuting or defending litigation, regulatory approvals and other regulatory filings and communications, and filing, prosecuting and enforcing Patents in connection with Receiving Party's rights and obligations pursuant to this License Agreement; and
- (c) in connection with exercising its rights hereunder, to its Affiliates; permitted acquirers or assignees; investment bankers, investors and lender; and in the case of Moderna, to its Approved Partners;
- provided that (1) with respect to Sections 9.4(a) or 9.4(b), where reasonably possible, Receiving Party will notify Disclosing Party of Receiving Party's intent to make any disclosure pursuant thereto sufficiently prior to making such disclosure so as to allow Disclosing Party adequate time to take whatever action it may deem appropriate to protect the confidentiality of the information to be disclosed, and (2) with respect to Section 9.4(c), each of those named people and entities are required to comply with the restrictions on use and disclosure in Section 9.2 (other than investment bankers, investors and lenders, which must be bound prior to disclosure by commercially reasonable obligations of confidentiality).
- 9.5 Terms of this License Agreement: Publicity. The Parties agree that the existence and terms of this License Agreement will be treated as Confidential Information of both Parties, and thus may be disclosed only as permitted by Section 9.4. Except as required by Law, each Party agrees not to issue any press release or public statement disclosing information relating to the existence of this License Agreement or the transactions contemplated hereby or the terms hereof without the prior written consent of the other Part.

10. Warranties; Limitations of Liability; Indemnification.

- 10.1 <u>Representations and Warranties</u>. Each Party represents and warrants to the other as of the License Agreement Effective Date that it has the legal right and power to enter into this License Agreement, to extend the rights and licenses granted or to be granted to the other in this License Agreement, and to fully perform its obligations hereunder.
- 10.2 <u>Additional Representations and Warranties of Acuitas</u>. Except as set forth in <u>Schedule 9.2</u>, Acuitas represents and warrants to Moderna that, as of the License Agreement Effective Date:
- (a) Licensed Technology. Appendix C sets forth a complete and accurate list of all Patents included in the Licensed Technology, indicating the owner, licensor and/or co-owner(s), if applicable. Acuitas Controls the Patents listed on Appendix C and the Know-How within the Licensed Technology, and is entitled to grant the licenses specified herein. To Acuitas' knowledge, the Patents listed on Appendix C have been procured or are being procured from the respective Patent offices in accordance with applicable Law. None of the Patents included in the Licensed Technology is or has been involved in any opposition, cancellation, interference, reissue or reexamination proceeding, and to Acuitas' knowledge no Licensed Technology is the subject of any judicial, administrative or arbitral order, award, decree, injunction, lawsuit, proceeding or

stipulation. Neither Acuitas nor any of its Affiliates has received any notice alleging that the Patents in the Licensed Technology are invalid or unenforceable, or challenging Acuitas' ownership of or right to use any such rights. In the event that Acuitas or its Affiliates directly or indirectly, grants, assign, licenses, sublicenses, encumbers or otherwise transfers (each, a "Transfer") to any Third Party any right, title or interest in or to the Licensed Proprietary Technology, such Transfer will be subject to the rights and licenses granted to Moderna and its Affiliates herein.

(b) Third Party Agreements. The Applicable In-Licenses are valid and binding obligations of Acuitas and, to the knowledge of Acuitas, the applicable licensor, enforceable against Acuitas and, to the Knowledge of Acuitas, the applicable licensor, in accordance with their terms, except as may be limited by general principles of equity (regardless of whether considered in a proceeding at law or in equity) and by applicable bankruptcy, insolvency, moratorium and other similar Laws of general application relating to or affecting creditors' rights generally.



- (c) Patents. To Acuitas' knowledge, the Patents listed on Appendix C have been procured or are being procured from the respective patent offices in accordance with applicable Law. None of the Patents included in the Licensed Technology is or has been involved in any opposition, cancellation, interference, reissue or reexamination proceeding, and no Licensed Technology is the subject of any judicial, administrative or arbitral order, award, decree, injunction, lawsuit, proceeding or stipulation. Neither Acuitas nor any of its Affiliates has received any notice alleging that the Patents in the Licensed Technology are invalid or unenforceable, or challenging Acuitas' ownership of or right to use any such rights.
- (d) Encumbrances. Except for the Third Party In-Licenses, Acuitas and its Affiliates are not subject to any payment obligations to Third Parties as a result of the execution or performance of this License Agreement. Neither Acuitas nor any of its Affiliates has granted any liens or security interests on the Licensed Technology and the Licensed Technology is to Acuitas' knowledge free and clear of any mortgage, pledge, claim, security interest, covenant, easement,

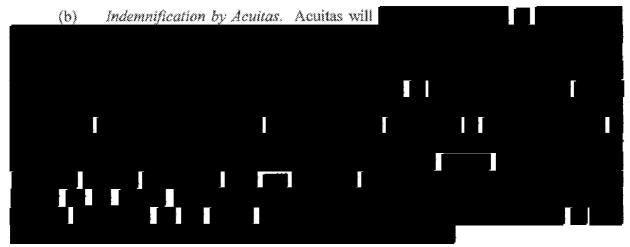
encumbrance, lien or charge of any kind. The foregoing shall not apply to any option or license agreement entered into by Acuitas prior to the Effective Date.

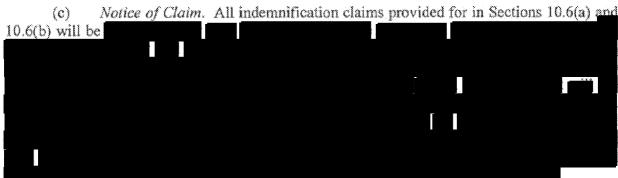
- (e) No Conflicts. The execution, delivery and performance by Acuitas of this License Agreement and the consummation of the transactions contemplated hereby will not result in any violation of, conflict with, result in a breach of or constitute a default under any understanding, contract or agreement to which Acuitas is a party or by which it is bound.
- (f) No Proceedings. There is no action, suit, proceeding or investigation pending or, to the knowledge of Acuitas, currently threatened in writing against or affecting Acuitas that questions the validity of this License Agreement or the right of Acuitas to enter into this License Agreement or consummate the transactions contemplated hereby.
- (g) Infringement. Neither Acuitas nor any of its Affiliates has received any notice of any claim that any Patent, Know-How or other intellectual property owned or controlled by a Third Party would be infringed or misappropriated by the Licensed Technology in the production, use, research, development, manufacture or commercialization of Licensed Product.
- 10.3 <u>Disclaimers</u>. Without limiting the respective rights and obligations of the Parties expressly set forth herein, each Party specifically disclaims any guarantee that any Licensed Product will be successful, in whole or in part. EXCEPT AS OTHERWISE EXPRESSLY PROVIDED IN THIS LICENSE AGREEMENT, THE PARTIES MAKE NO REPRESENTATIONS AND EXTEND NO WARRANTY OF ANY KIND, EITHER EXPRESS OR IMPLIED.
- 10.4 No Consequential Damages. NOTWITHSTANDING ANYTHING IN THIS AGREEMENT OR OTHERWISE, NEITHER PARTY WILL BE LIABLE TO THE OTHER OR ANY THIRD PARTY WITH RESPECT TO ANY SUBJECT MATTER OF THIS AGREEMENT FOR ANY INDIRECT, PUNITIVE, SPECIAL OR CONSEQUENTIAL DAMAGES, EVEN IF SUCH PARTY HAS BEEN INFORMED OR SHOULD HAVE KNOWN OF THE POSSIBILITY OF SUCH DAMAGES; PROVIDED THAT THIS SECTION 10.4 WILL NOT APPLY TO BREACHES OF A PARTY'S CONFIDENTIALITY OBLIGATIONS OR THE PARTIES' INDEMNIFICATION RIGHTS AND OBLIGATIONS UNDER SECTION 10.6.
- 10.5 <u>Performance by Others</u>. The Parties recognize that each Party may perform some or all of its obligations under this License Agreement through Affiliates and permitted subcontractors provided, however, that each Party will remain responsible and liable for the performance by its Affiliates and permitted subcontractors and will cause its Affiliates and permitted subcontractors to comply with the provisions of this License Agreement in connection therewith.

10.6 Indemnification.

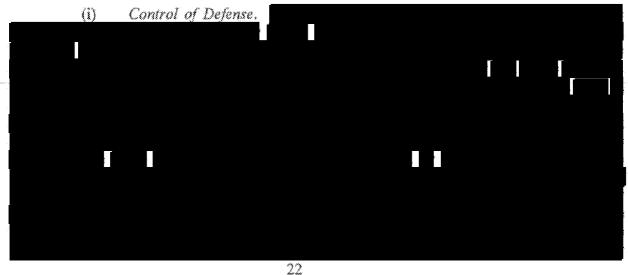
(a) Indemnification by Moderna. Moderna will indemnify Acuitas, its Affiliates and their respective directors, officers, employees, Third Party licensors and agents, and their respective successors, heirs and assigns (collectively, "Acuitas Indemnitees"), and defend and save each of them harmless, from and against any and all losses, damages, liabilities, costs and expenses (including reasonable attorneys' fees and expenses) (collectively, "Losses") in connection with any and all suits, investigations, claims or demands of Third Parties (collectively, "Third Party Claims") against the Acuitas Indemnitees arising from or occurring as a result of: (i) the material breach by Moderna of any term of this License Agreement; (ii) any gross negligence or willful misconduct on the part of Moderna in performing its obligations under this License Agreement;

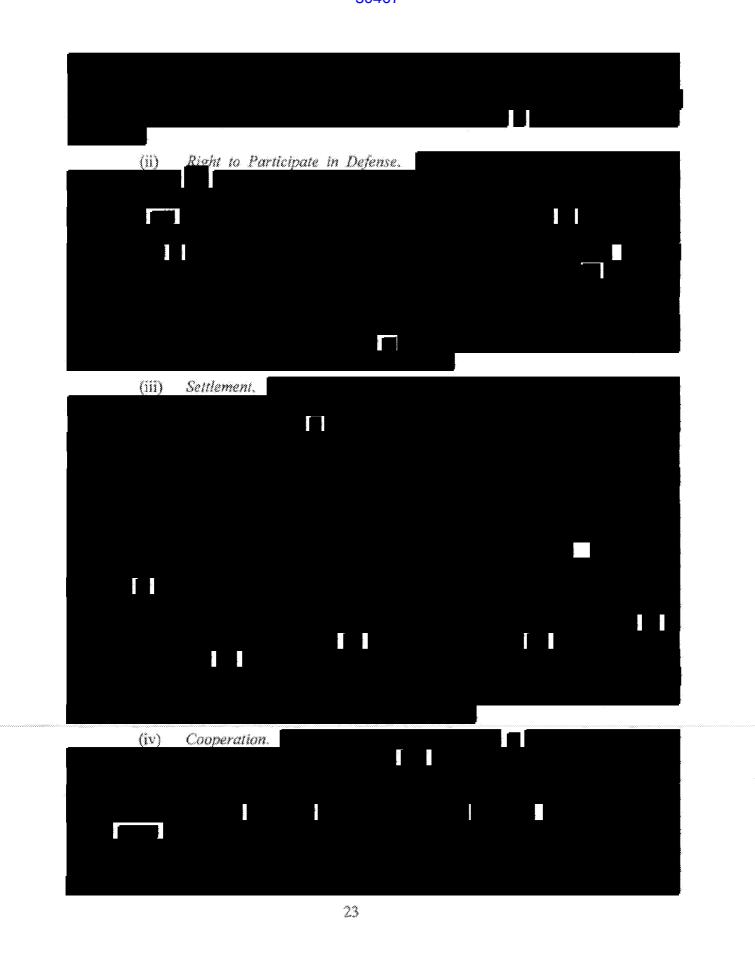
or (iii) the Development or Commercialization by or on behalf of Moderna or any of its Affiliates or Sublicensees of Licensed Product, except in each case for those Losses for which Acuitas has an obligation to indemnify Moderna pursuant to Section 10.6(b), as to which Losses each Party will indemnify the other to the extent of their respective liability; provided, however, that Moderna will not be obligated to indemnify Acuitas Indemnitees for any Losses to the extent that such Losses arise as a result of gross negligence or willful misconduct on the part of an Acuitas Indemnitee.

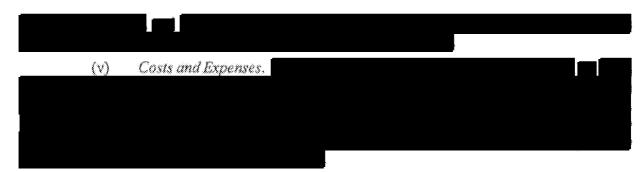




(d) Defense, Settlement, Cooperation and Expenses.







Insurance. Each Party will maintain at its sole cost and expense, an adequate liability insurance or self-insurance program (including product liability insurance) to protect against potential liabilities and risk arising out of activities to be performed under this License Agreement, and any agreement related hereto and upon such terms (including coverages, deductible limits and self-insured retentions) as are customary in the U.S. pharmaceutical industry for the activities to be conducted by such Party under this License Agreement. Subject to the preceding sentence, such liability insurance or self-insurance program will insure against all types of liability, including personal injury, physical injury or property damage arising out of the manufacture, sale, use, distribution or marketing of Licensed Product. The coverage limits set forth herein will not create any limitation on a Party's liability to the other under this License Agreement.

11. Term and Termination.

11.1 Term. This License Agreement will commence as of the License Agreement Effective Date and, unless sooner terminated in accordance with the terms hereof or by mutual written consent, will continue on a country-by-country basis, until there are no more payments owed Acuitas on Licensed Product in such country (the longest such period of time for any Licensed Product hereunder, the "Term"). Upon there being no more such payments hereunder for any such Licensed Product in such country, the licenses contained in Section 3.1 for such Licensed Product will become fully paid up and will remain non-exclusive and in effect with respect to such Licensed Product in such country.

11.2 Termination by Acuitas.

(a) Breach. Acuitas will have the right to terminate this License Agreement in full upon delivery of written notice to Moderna in the event of any material breach by Moderna of any terms and conditions of this License Agreement, provided that such termination will not be effective if such breach, has been cured within days after written notice thereof is given by Acuitas to Moderna specifying the nature of the alleged breach.

11.3 Termination by Moderna.

- (a) Breach. Moderna will have the right to terminate this License Agreement in full upon delivery of written notice to Acuitas in the event of any material breach by Acuitas of any terms and conditions of this License Agreement, provided that such termination will not be effective if such breach has been cured within days after written notice thereof is given by Moderna to Acuitas specifying the nature of the alleged breach.
- (b) Discretionary Termination. Moderna will have the right to terminate this License Agreement in full at its discretion for any reason by delivering written notice to Acuitas, such termination to be effective days following the date of such notice.

(c) Alternative to Termination Under Section 11.3(a). If Moderna has the right to terminate this License Agreement under Section 11.3(a) as a result of a material breach by Acuitas (including following expiration of all applicable cure periods thereunder) that fundamentally impairs the value of Moderna's rights hereunder with respect to the Licensed Target, then Moderna may, in lieu of exercising such termination right, elect by written notice to Acuitas before the end of such applicable cure period to have this License Agreement continue in full force and effect for the Term, provided that the following will apply:



11.4 Termination Upon Bankruptcy.

- (a) Termination Right. Either Party may terminate this License Agreement if, at any time, the other Party will file in any court or agency pursuant to any statute or regulation of any state, country or jurisdiction, a petition in bankruptcy or insolvency or for reorganization or for an arrangement or for the appointment of a receiver or trustee of that Party or of its assets, or if the other Party proposes a written agreement of composition or extension of its debts, or if the other Party will be served with an involuntary petition against it, filed in any insolvency proceeding, and such petition will not be dismissed within days after the filing thereof, or if the other Party will propose or be a Party to any dissolution or liquidation, or if the other Party will make an assignment for the benefit of its creditors.
- (b) Consequences of Bankruptcy. All rights and licenses granted under or pursuant to this License Agreement by Acuitas or its Affiliates are, and will otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code, licenses of right to "intellectual property" as defined under Section 101 of the U.S. Bankruptcy Code. The Parties agree that Moderna and its Affiliates and Sublicensees, as licensees of such rights under this License Agreement, will retain and may fully exercise all of their rights and elections under the U.S. Bankruptcy Code and any foreign counterparts thereto subject to the payment of amounts provided for herein.
- 11.5 <u>Effects of Termination</u>. Upon termination (but not expiration pursuant to Section 11.1) of this License Agreement for any reason:

- (a) Cessation of Rights. Except as otherwise expressly provided herein, all rights and licenses granted by Acuitas to Moderna in Section 3.1 will terminate, and Moderna and its Affiliates and Sublicensees will cease all use of Licensed Technology.
- (b) Country Termination. If this License Agreement is terminated only with respect to a specific country or a specific Licensed Product pursuant to Section 11.2(a), the provisions of this Section 11.5 will apply only with respect to such terminated country and such Licensed Product.
- 11.6 <u>Survival</u>. In addition to the termination consequences set forth in Section 11.5, the following provisions will survive termination or expiration of this License Agreement: Sections 1, 3.2, 3.5(b)(iv), 6, 9, 10.6, 11.5, 11.6 and 12. Termination or expiration of this License Agreement will not relieve the Parties of any liability or obligation which accrued hereunder prior to the effective date of such termination or expiration nor preclude either Party from pursuing all rights and remedies it may have hereunder or at law or in equity with respect to any breach of this License Agreement nor prejudice either Party's right to obtain performance of any obligation. All other rights and obligations will terminate upon expiration of this License Agreement.

12. General Provisions.

12.1 Dispute Resolution.

- (a) Disputes. Disputes arising under or in connection with this License Agreement will be resolved pursuant to this Section 12.1; provided, however, that in the event a dispute cannot be resolved without an adjudication of the rights or obligations of a Third Party (other than any Moderna Indemnitees or Acuitas Indemnitees identified in Section 10.6), the dispute procedures set forth Sections 12.1(c) and 12.1(c) will be inapplicable as to such dispute.
- (b) Dispute Escalation. In the event of a dispute between the Parties, the Parties will first attempt in good faith to resolve such dispute by negotiation and consultation between themselves. In the event that such dispute is not resolved on an informal basis within days, any Party may, by written notice to the other, have such dispute referred to each Party's who will attempt in good faith to resolve such dispute by negotiation and consultation for a day period following receipt of such written notice
- (c) Dispute Resolution. In the event the figure was a set of the Parties are not able to resolve such dispute as set forth above, the figure will together elect whether to submit the dispute to moderation, litigation or arbitration. In the absence of such an agreement, either party may elect to initiate litigation.
- (d) Injunctive Relief. Notwithstanding the dispute resolution procedures set forth in this Section 12.1, in the event of an actual or threatened breach hereunder, the aggrieved Party may seek equitable relief (including restraining orders, specific performance or other injunctive relief) in any court or other forum, without first submitting to any dispute resolution procedures hereunder.
- (e) Tolling. The Parties agree that all applicable statutes of limitation and time-based defenses (such as estoppel and laches) will be tolled while the dispute resolution procedures set forth in this Section 12.1 are pending, and the Parties will cooperate in taking all actions reasonably necessary to achieve such a result.
 - (f) Prevailing Party. The prevailing Party in any arbitration under Section 12.1(c) or

any other suit related to this License Agreement will be entitled to recover from the losing Party all out-of-pocket fees, costs and expenses (including those of attorneys, professionals and accountants and all those arising from appeals and investigations) incurred by the prevailing Party in connection with such arbitration or suit.

- Parties hereunder will be cumulative and in addition to all other rights and remedies provided hereunder or available by agreement, at Law or otherwise. Each Party acknowledges and agrees that breach of any of the terms or conditions of this License Agreement may cause irreparable harm and damage to the other and that such damage may not be ascertainable in money damages and that as a result thereof the non-breaching Party may be entitled to seek from a court equitable or injunctive relief restraining any breach or future violation of the terms contained herein by the breaching Party without the necessity of proving actual damages or posting bond. Such right to equitable relief is in addition to whatever remedies either Party may be entitled to as a matter of Law or equity, including money damages.
- 12.3 Relationship of Parties. Nothing in this License Agreement is intended or will be deemed to constitute a partnership, agency, employer-employee or joint venture relationship between the Parties. No Party will incur any debts or make any commitments for the other, except to the extent, if at all, specifically provided therein. Except as may be required by the Applicable In-Licenses, there are no express or implied third party beneficiaries hereunder (except for Moderna Indemnitees and Acuitas Indemnitees for purposes of Section 10.6). For clarity, Moderna does not grant to Acuitas any rights or licensed under this License Agreement to any Moderna technology or intellectual property rights.
- 12.4 <u>Compliance with Law</u>. Each Party will perform or cause to be performed any and all of its obligations or the exercise of any and all of its rights hereunder in good scientific manner and in compliance with all applicable Law.
- 12.5 Governing Law. This License Agreement will be governed by and construed in accordance with the Laws of the State of New York, without respect to its conflict of Laws rules, provided that any dispute relating to the scope, validity, enforceability or infringement of any Patents or Know-How will be governed by, and construed and enforced in accordance with, the substantive Laws of the jurisdiction in which such Patents or Know-How apply.
- 12.6 <u>Counterparts</u>; <u>Facsimiles</u>. This License Agreement may be executed in one or more counterparts, each of which will be deemed an original, and all of which together will be deemed to be one and the same instrument. Facsimile or PDF execution and delivery of this License Agreement by either Party will constitute a legal, valid and binding execution and delivery of this License Agreement by such Party
- 12.7 <u>Headings</u>. All headings in this License Agreement are for convenience only and will not affect the meaning of any provision hereof.
- 12.8 <u>Waiver of Rule of Construction</u>. Each Party has had the opportunity to consult with counsel in connection with the review, drafting and negotiation of this License Agreement. Accordingly, the rule of construction that any ambiguity in this License Agreement will be construed against the drafting party will not apply.
- 12.9 <u>Interpretation</u>. Whenever any provision of this License Agreement uses the term "including" (or "includes"), such term will be deemed to mean "including without limitation"

(or "includes without limitations"). "Herein," "hereby," "hereunder," "hereof" and other equivalent words refer to this License Agreement as an entirety and not solely to the particular portion of this License Agreement in which any such word is used. All definitions set forth herein will be deemed applicable whether the words defined are used herein in the singular or the plural. Unless otherwise provided, all references to Sections and Exhibits in this License Agreement are to Sections and Exhibits of this License Agreement. References to any Sections include Sections and subsections that are part of the related Section (e.g., a section numbered "Section 2.1" would be part of "Section 2" and references to "Section 2" would also refer to material contained in the subsection described as "Section 2.1(a).")

- 12.10 <u>Binding Effect</u>. This License Agreement will inure to the benefit of and be binding upon the Parties, their Affiliates, and their respective lawful successors and assigns.
- 12.11 <u>Assignment</u>. This License Agreement may not be assigned by either Party, nor may either Party delegate its obligations or otherwise transfer licenses or other rights created by this License Agreement, except as expressly permitted hereunder or otherwise without the prior written consent of the other Party, which consent will not be unreasonably withheld; provided that either Party may assign this License Agreement to an Affiliate or to its successor in connection with sale of all or substantially all of its assets or business or that portion of its business pertaining to the subject matter of this License Agreement (whether by merger, consolidation or otherwise).
- 12.12 Notices. All notices, requests, demands and other communications required or permitted to be given pursuant to this License Agreement will be in writing and will be deemed to have been duly given upon the date of receipt if delivered by hand, recognized international overnight courier, confirmed facsimile transmission, or registered or certified mail, return receipt requested, postage prepaid to the following addresses or facsimile numbers:

If to Moderna: Moderna Therapeutics, Inc.

200 Technology Square Cambridge, MA 02139

Attention:

With a copy to: Moderna Therapeutics, Inc.

320 Bent Street

Cambridge, MA 02139

Attention:

If to Acuitas: Acuitas Therapeutics Inc.

2714 West 31rst Avenue

Vancouver, B.C. Canada V6<u>L 2A1</u>

Attention:

With a copy to: McCarthy Tetrault LLP

Suite 2400 745 Thurlow Street

Vancouver, B.C. Canada V6E 0C5

Attention:

Either Party may change its designated address and facsimile number by notice to the other Party in the manner provided in this Section 12.12.

- 12.13 Amendment and Waiver. This License Agreement may be amended, supplemented, or otherwise modified only by means of a written instrument signed by both Parties; provided that any unilateral undertaking or waiver made by one Party in favor of the other will be enforceable if undertaken in a writing signed by the Party to be charged with the undertaking or waiver. Any waiver of any rights or failure to act in a specific instance will relate only to such instance and will not be construed as an agreement to waive any rights or fail to act in any other instance, whether or not similar.
- 12.14 <u>Severability</u>. In the event that any provision of this License Agreement will, for any reason, be held to be invalid or unenforceable in any respect, such invalidity or unenforceability will not affect any other provision hereof, and the Parties will negotiate in good faith to modify the License Agreement to preserve (to the extent possible) their original intent.
- 12.15 <u>Entire License Agreement</u>. This License Agreement together with the Development and Option Agreement any other License Agreements entered into during the Term are the sole agreement with respect to the subject matter and supersedes all other agreements and understandings between the Parties with respect to same.
- 12.16 Force Majeure. Neither Acuitas nor Moderna will be liable for failure of or delay in performing obligations set forth in this License Agreement (other than any obligation to pay monies when due), and neither will be deemed in breach of such obligations, if such failure or delay is due to natural disasters or any causes reasonably beyond the control of Acuitas or Moderna; provided that the Party affected will promptly notify the other of the force majeure condition and will exert reasonable efforts to eliminate, cure or overcome any such causes and to resume performance of its obligations as soon as possible.

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WITNESS WHEREOF, the Parties have caused this License Agreement to be executed by their respective duly authorized officers as of the License Agreement Effective Date.

ACUITAS THERAPEUTICS INC.

Ву:			
Name:			
Title:			

Moderna Therapeutics, Inc.

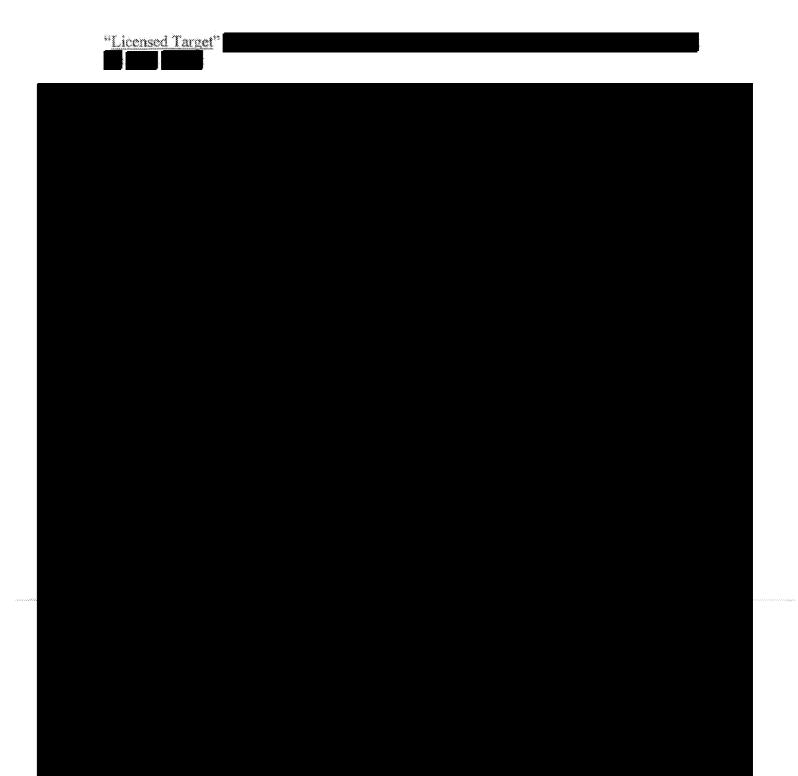
By:

Name:

Title:

Date: 14445+ 14 2016

<u>Appendix A</u> Licensed Target



LICENSE AGREEMENT



Appendix B Applicable In-Licenses



Appendix C

Certain Patents within the Licensed Technology as of the License Agreement Effective Date



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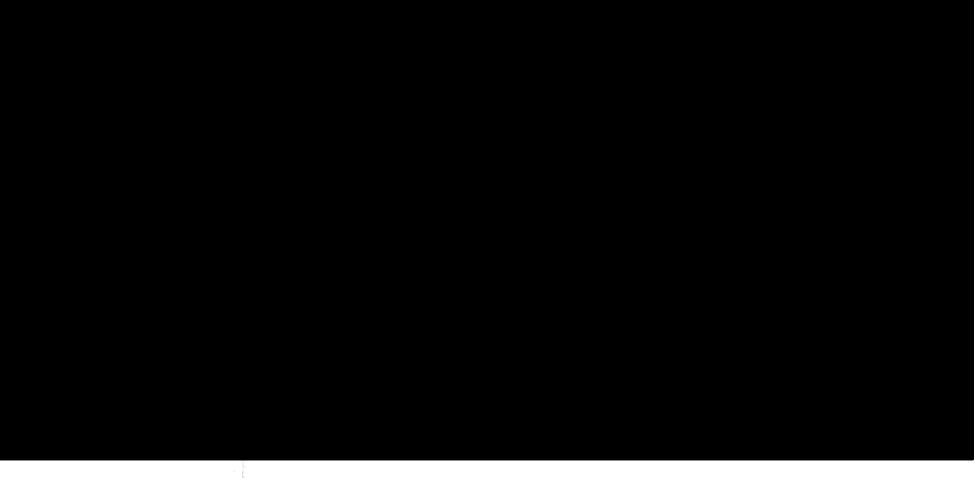
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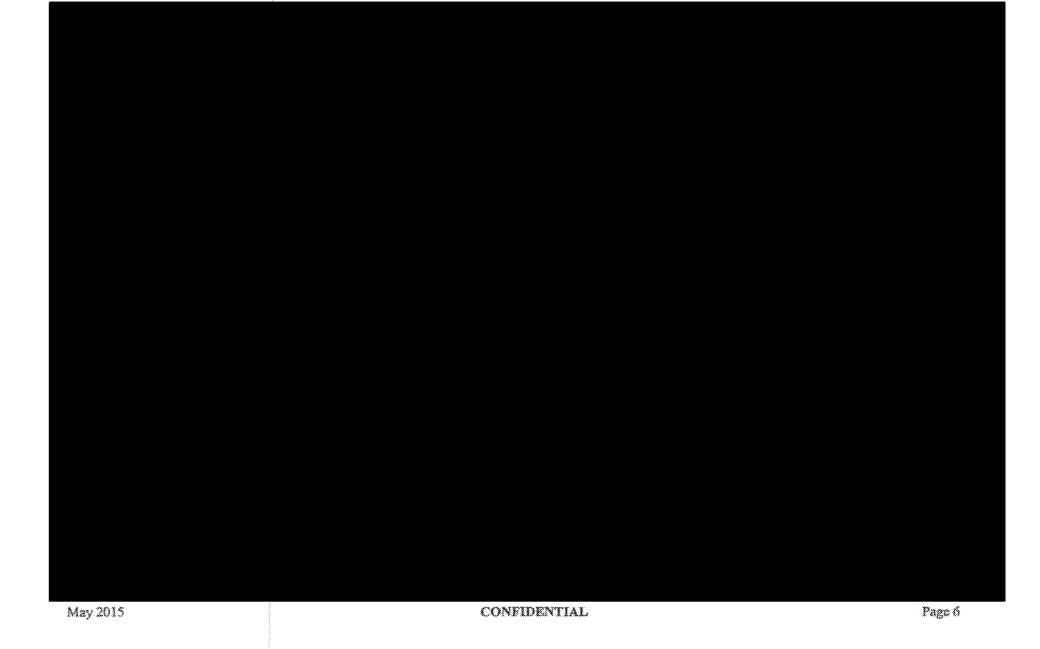
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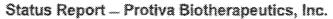
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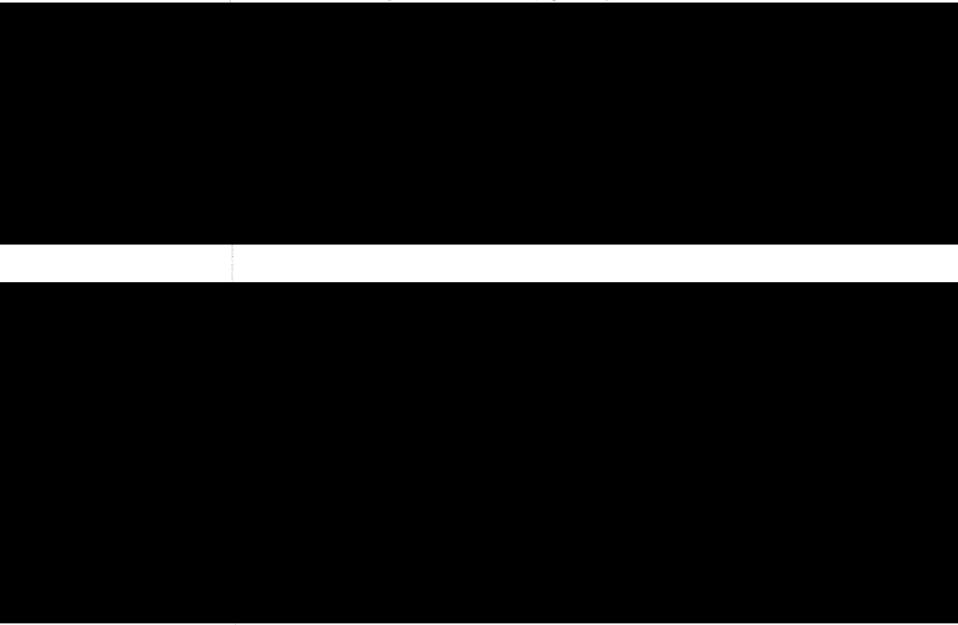
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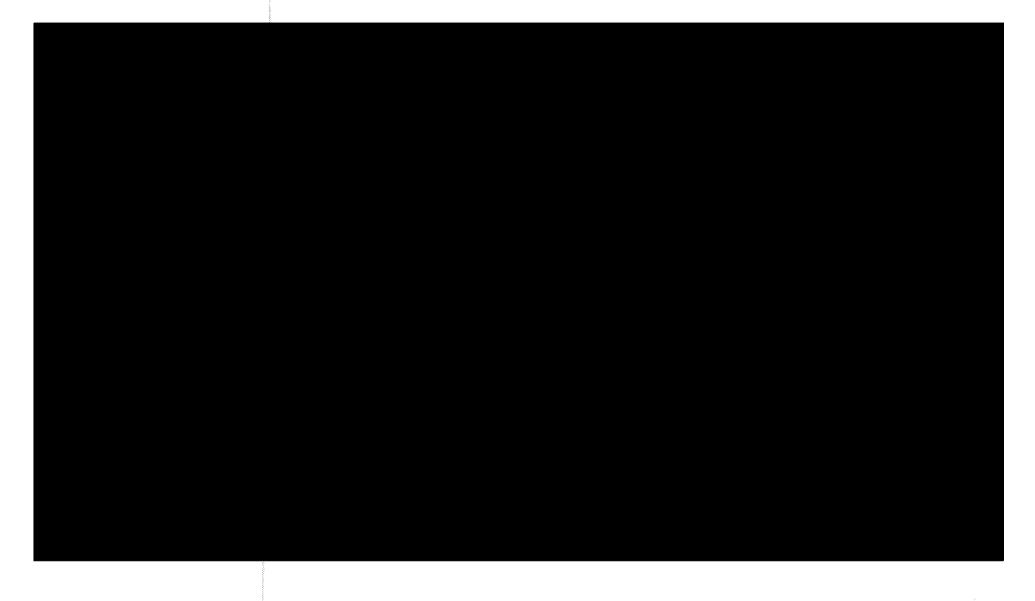


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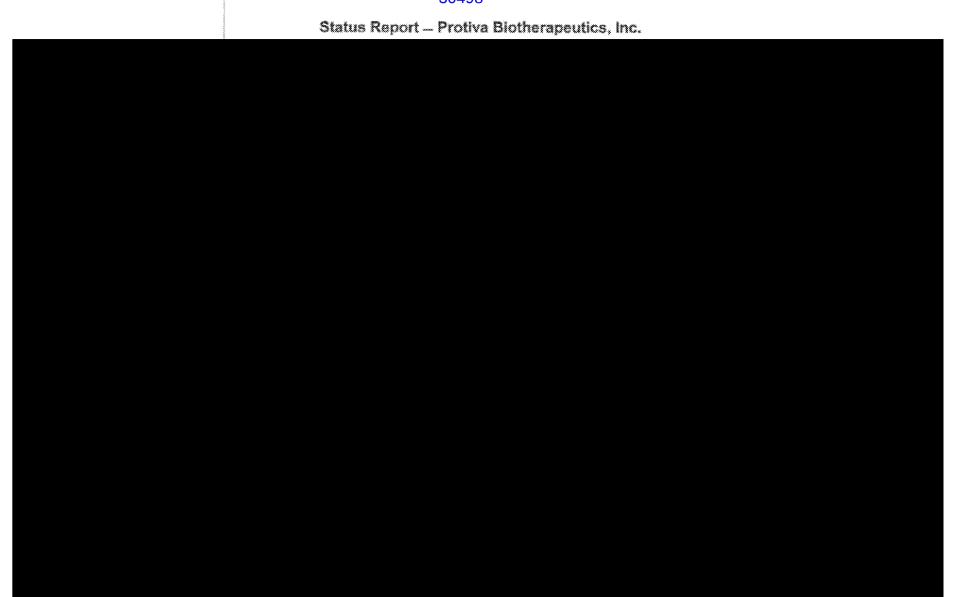
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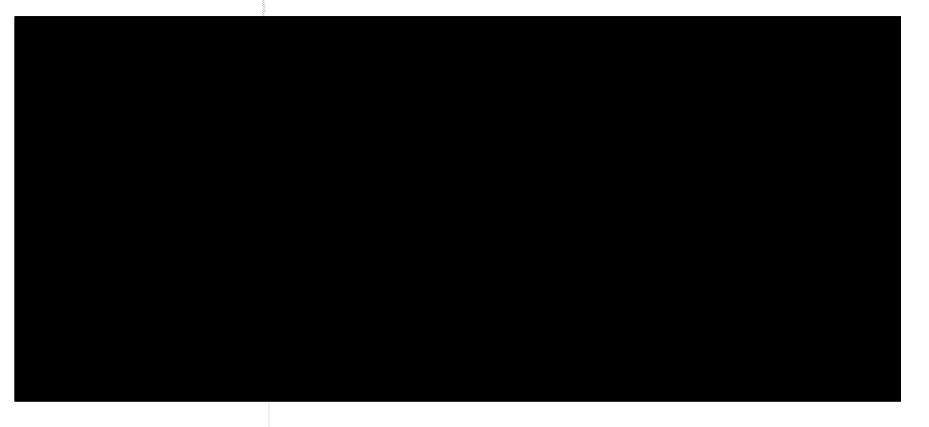
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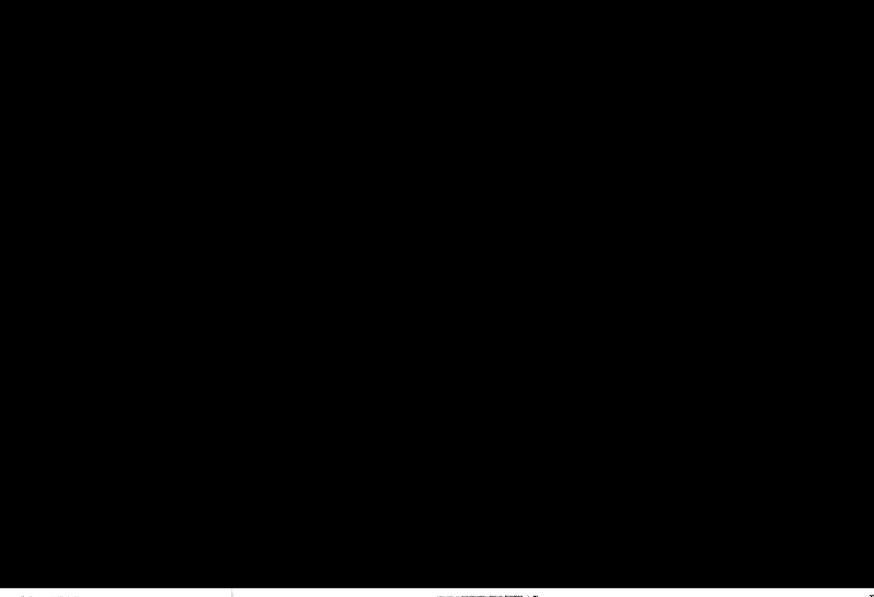


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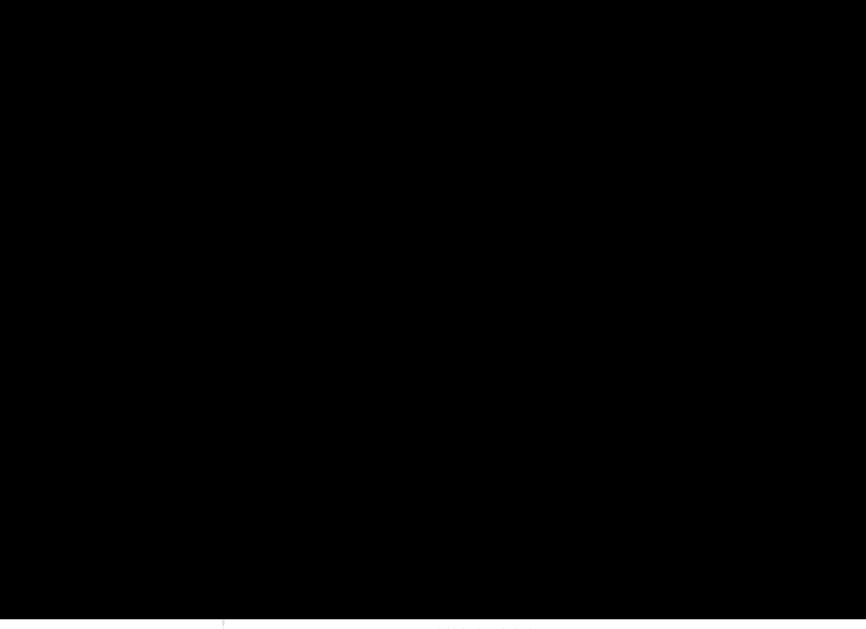
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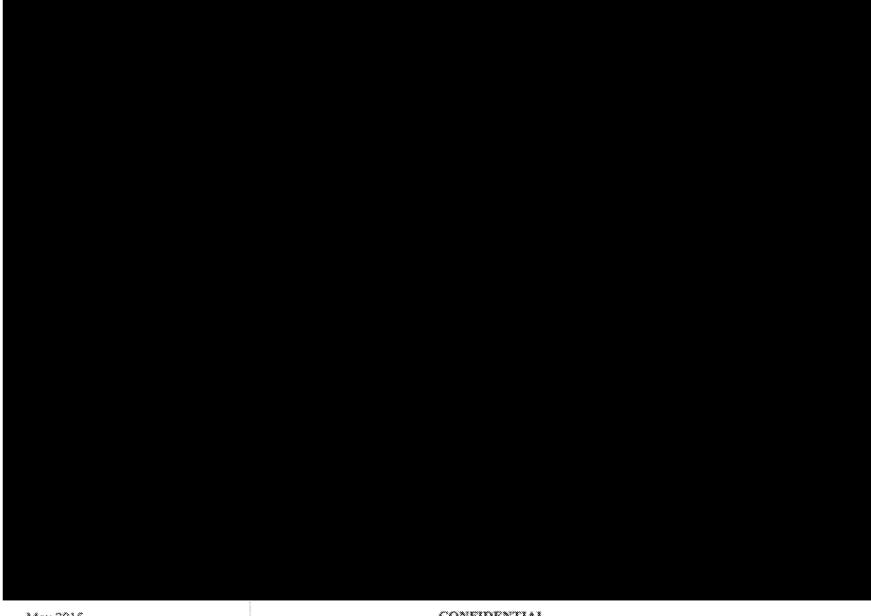
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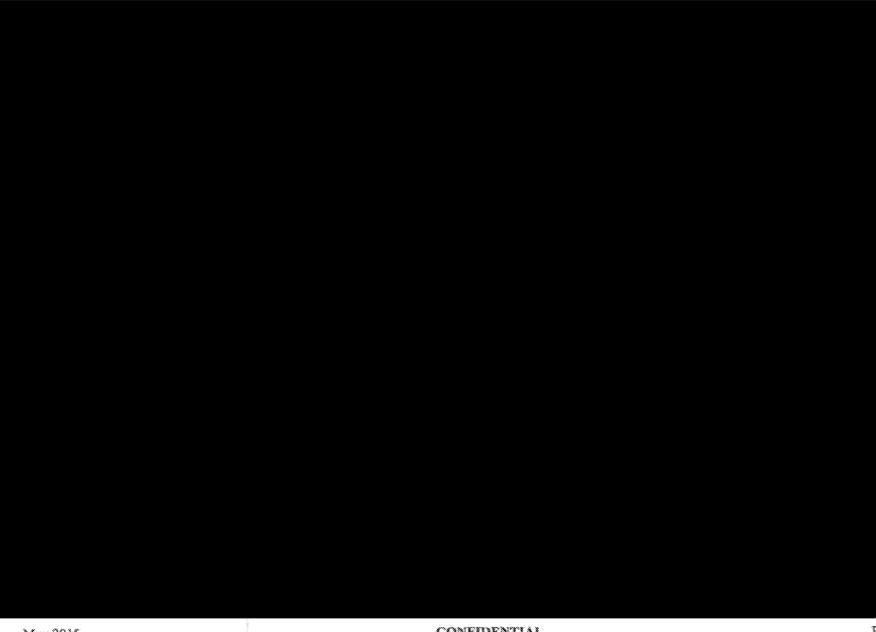
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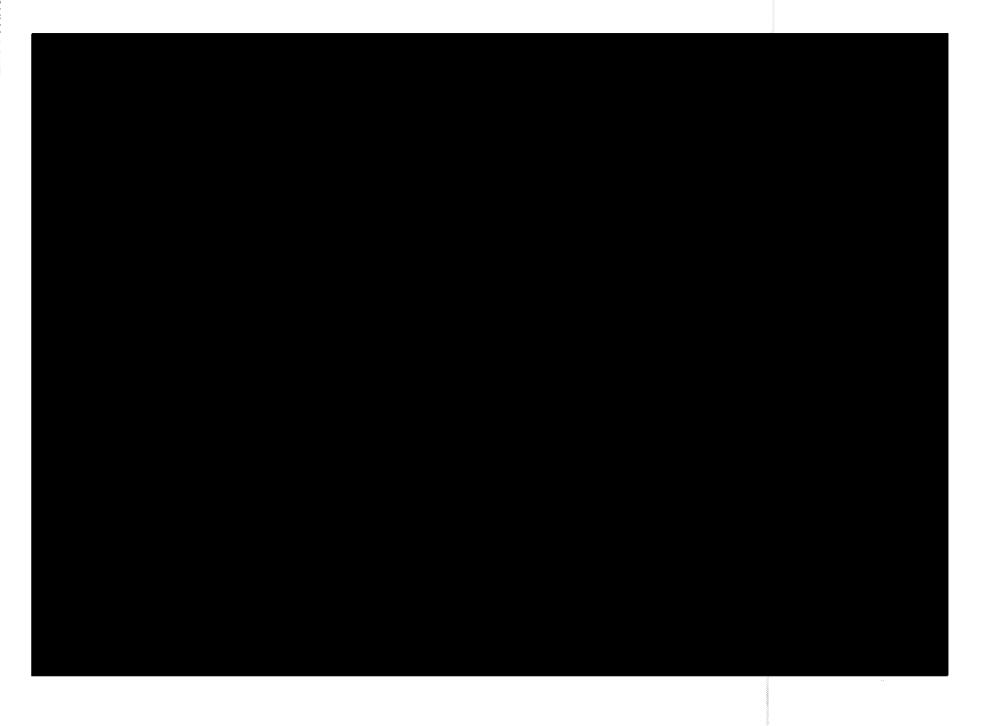
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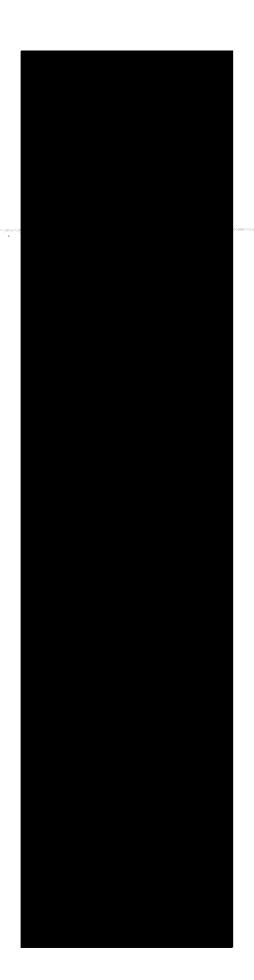


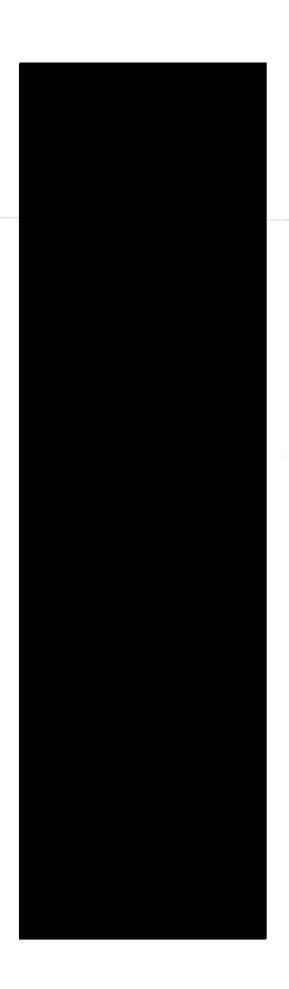












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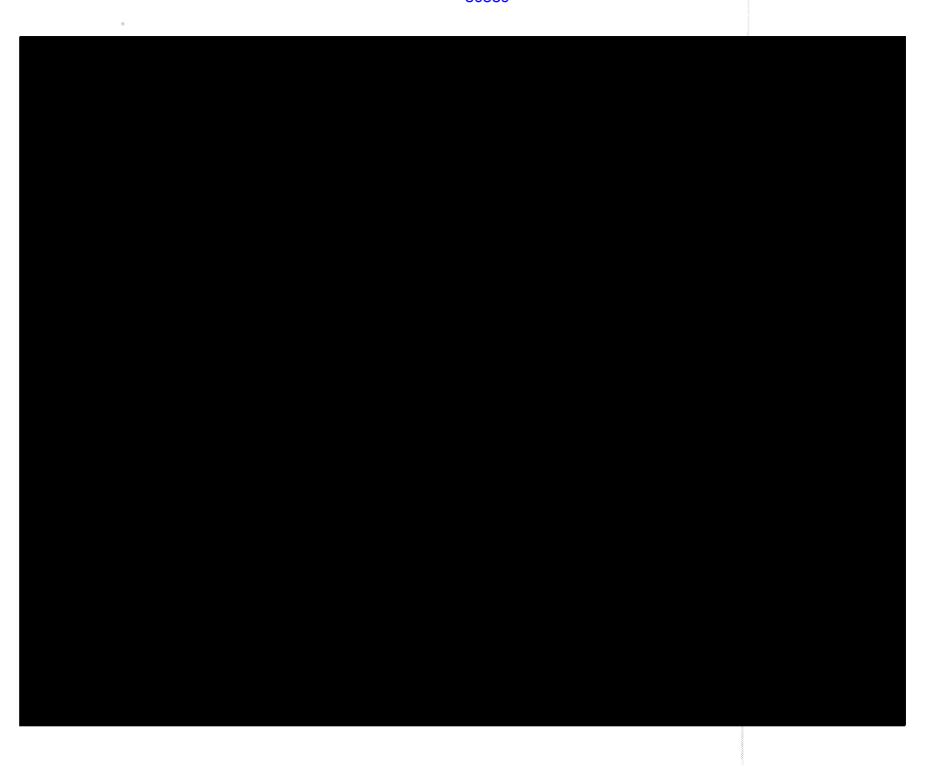


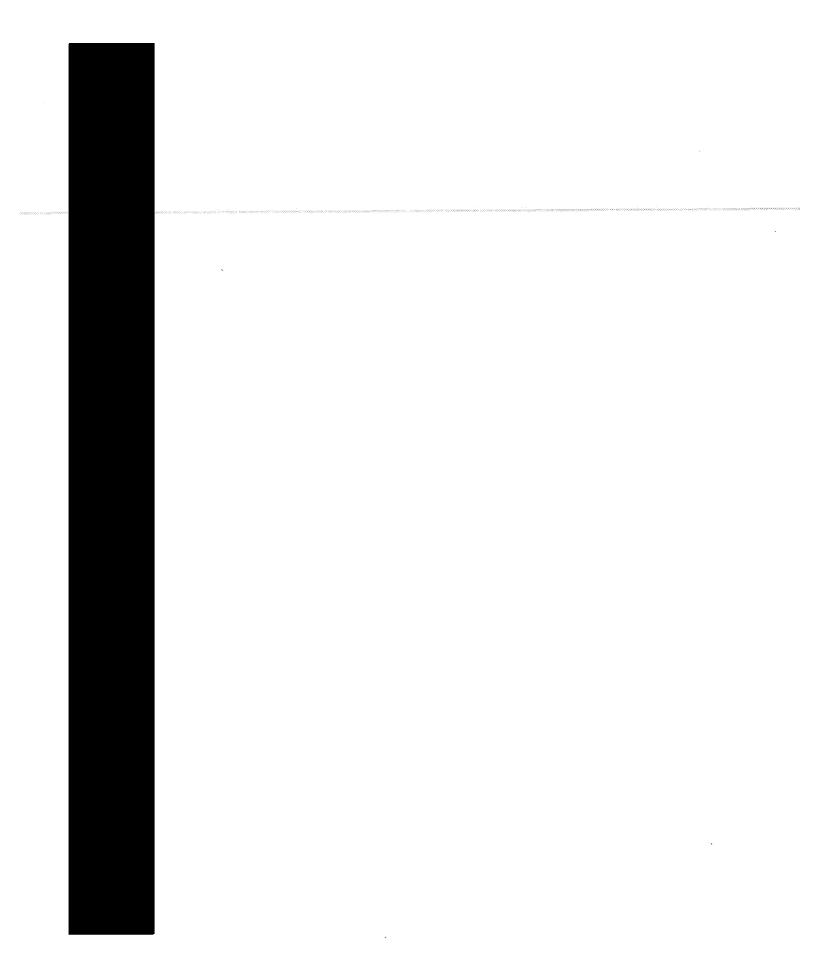
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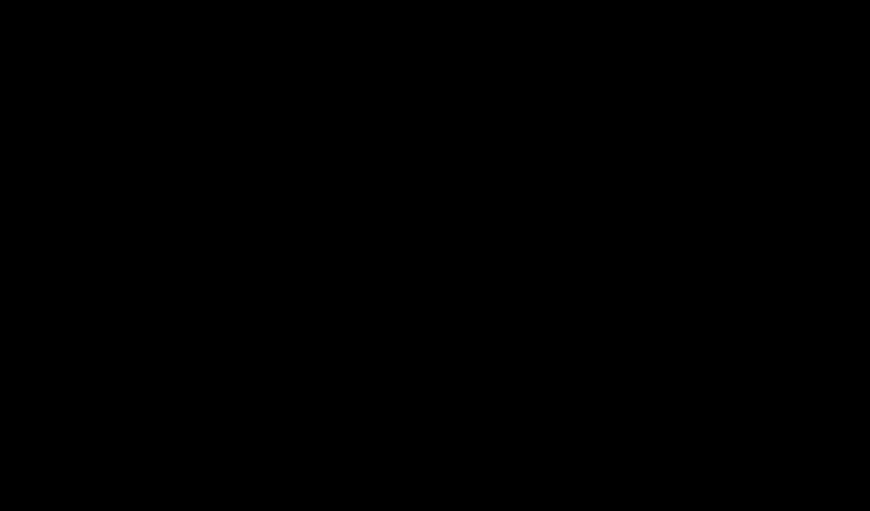


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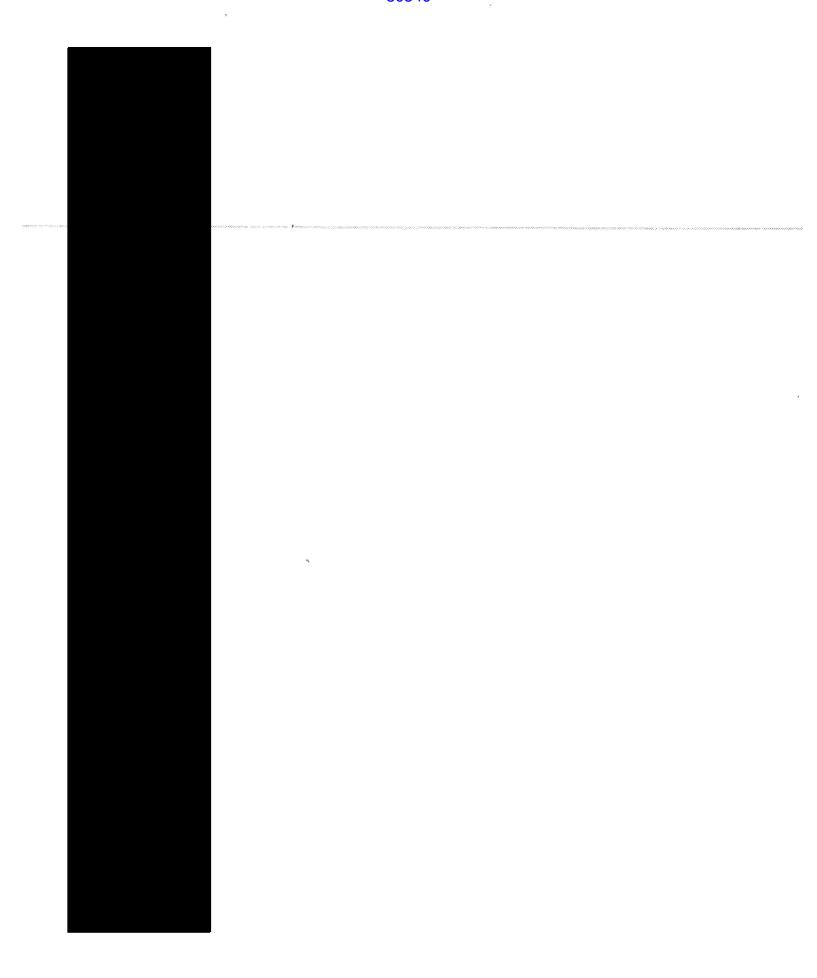


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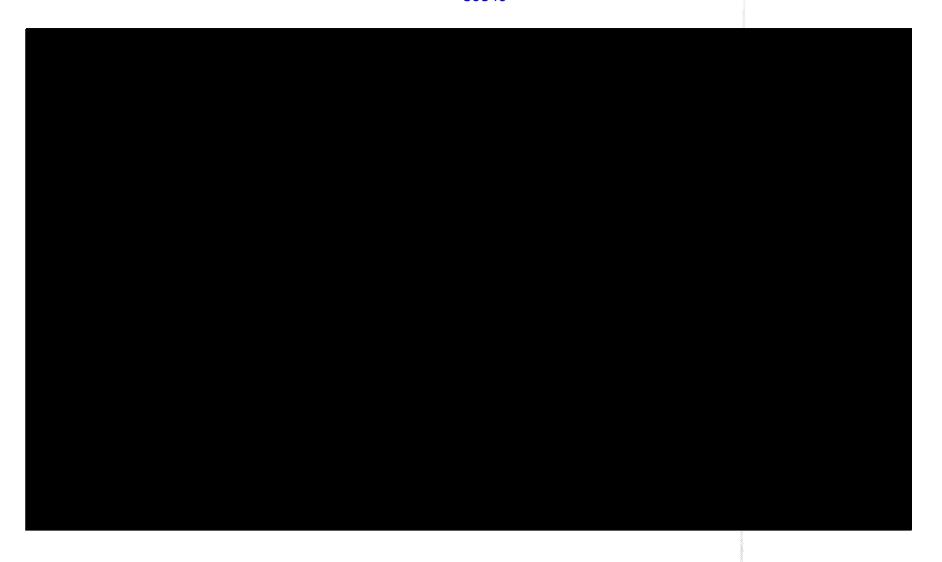
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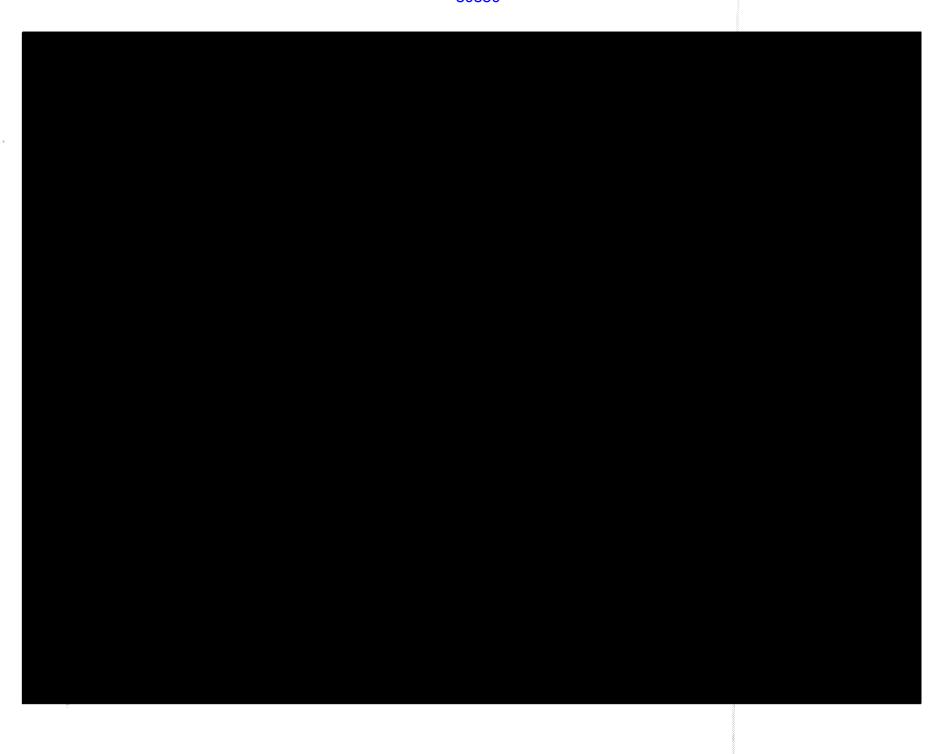
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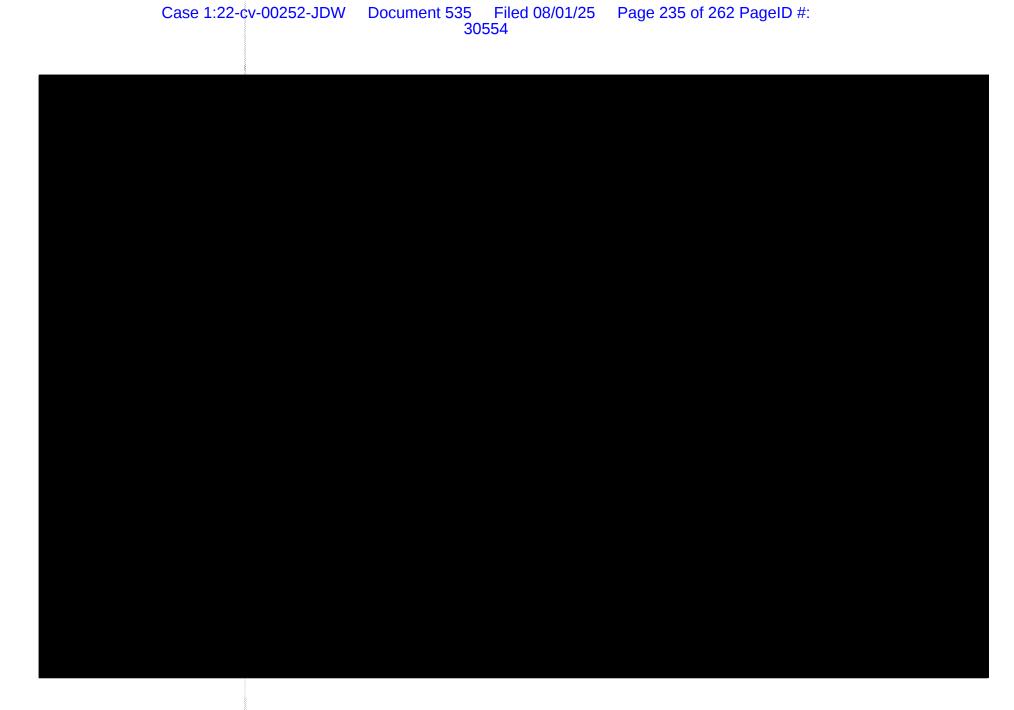














Schedule 9.2

Exceptions to Acuitas' Representations and Warranties in Section 9.2



EXHIBIT 25

ModernaTX, Inc. et al. v. Pfizer Inc. et al. Highly Confidential - Under the Protective Order Sunny Himansu

Page 1

UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF MASSACHUSETTS

- - - - - - - - - - - - - - - - X

MODERNATX, INC., and MODERNA US, INC., :

Plaintiff, :

v. : Civil Action No.

PFIZER INC., BIONTECH SE, BIONTECH : 1:22-cv-11378-RGS

MANUFACTURING GMBH, and BIONTECH :

US INC.,

Defendants.

- - - - - - - - - - - - - - - - - X

HIGHLY CONFIDENTIAL

UNDER THE PROTECTIVE ORDER

Videotaped deposition of Moderna by Sunny Himansu

Boston, Massachusetts

November 17, 2023

9:11 a.m.

Reported By: Alan H. Brock, RDR, CRR

DIGITAL EVIDENCE GROUP

1730 M Street, NW, Suite 812

Washington, D.C. 20036

(202) 232-0646

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ModernaTX, Inc. et al. v. Pfizer Inc. et al. Highly Confidential - Under the Protective Order

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Sunny Himansu

- 1 A. What was known as of 2015 is the virus binds
- 2 to the DPP4 receptor, and then they together are
- 3 involved in entry into the cell.
- 4 Q. And when you say binds, this was the spike
- 5 protein of the virus binds to the DPP4 receptor;
- 6 right?
- 7 A. The spike protein on the virion binds to the
- 8 DPP4 receptor.
- 9 Q. And that was known as of 2015; correct?
- 10 A. Correct.
- 11 Q. Now if we go to column 36. I just want to be
- 12 clear: SARS-CoV-2, we can agree it is not a strain of
- 13 SARS-CoV-1; right?
- 14 A. That is correct.
- 15 Q. All right, let's go to column 41. You say,
- line 17 on column 41, "The LNP used in the studies
- described herein has been used previously to delivery
- 18 siRNA in various animal models as well as in humans."
- 19 Do you see that?
- 20 A. Yes.
- 21 Q. So in your examples you were using the same
- 22 LNP that had been previously used and published for
- 23 siRNA?
- MR. PRUSSIA: Object to the form.
- 25 A. We had used LNPs -- again, that Moderna was

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Sunny Himansu

- 1 using at the time as a standard LNP and LNP
- 2 composition for vaccines. Some of these lipids have
- 3 been tested previously with siRNA, but for a
- 4 completely different purpose. SiRNA -- this is
- 5 completely different technology and learnings from
- 6 that do not translate to protein expression or vaccine
- 7 design. They're shutting down protein expression,
- 8 silencing something. With RNA technology you're
- 9 trying to express a protein to elicit an immune
- 10 response, versus with siRNA you're shutting something
- 11 down. So there's no cross-learning on the likelihood
- 12 of one working to the other.
- 13 Q. So no cross-learning whatsoever.
- 14 A. Correct.
- 15 Q. But you did use the same LNPs with the mRNA
- 16 that had been used with the siRNA; right?
- MR. PRUSSIA: Object to the form.
- 18 A. Correct, because the only learnings from
- 19 there would be the RNA charge that will be involved in
- 20 formation of LNPs.
- 21 Q. And the RNA charge that would be involved in
- 22 the formation of LNPs, that was known as of 2015;
- 23 right?
- 24 A. I would believe so, but that would again only
- 25 help us in confirming what lipids could form, but not

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Sunny Himansu

- 1 what lipids could be effective as vaccines.
- 2 Q. So, but you took the same lipid that had been
- 3 used in siRNA, you applied it to the mRNA, and it
- 4 encapsulated; right?
- 5 MR. PRUSSIA: Object to the form.
- 6 A. I took the LNP that was given to me by
- 7 Moderna as their standard platform technology and
- 8 applied that. I have no idea what other background,
- 9 you know --
- 10 Q. Well, I'm going to show you some things in
- 11 your patent that hopefully will make you understand.
- 12 Are you testifying that, sitting here today, you don't
- 13 know the background of the LNP that was used in your
- 14 patent?
- 15 A. I'm aware of the background of the LNP that
- 16 was used in the patent. You may be referring to the
- 17 lipid component of that LNP.
- 18 Q. I'm referring to the entire LNP formulation.
- 19 A. I'm completely confident and I'm aware of the
- 20 entire LNP composition that was used in this -- for
- 21 this vaccine, correct.
- 22 Q. And example 24 in particular, in 3, they tell
- 23 you the LNP; right?
- 24 A. Well, the claim, claim --
- 25 Q. You're going to the claim. I want to talk

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Sunny Himansu

- 1 about an actual composition. If we go to --
- 2 A. The claims describe the LNPs.
- 3 Q. The claims describe the LNPs? Or they claim
- 4 the LNPs?
- 5 A. They claim.
- 6 Q. Okay, let's talk about the LNPs you actually
- 7 described using. Let's go to column 212: This is
- 8 where we're getting into the betacoronavirus studies,
- 9 column 212, line 47. "In experiments where a lipid
- 10 nanoparticle formulation is used, the formulation may
- 11 include a cationic lipid, non-cationic lipid, PEG
- 12 lipid and structural lipid in the ratio 50 to 10 to
- 13 1.5 to 38.5." You go on to specify, "The cationic
- 14 lipid, the non-cationic lipid (DSPC), the PEG lipid,
- 15 and the structural lipid is cholesterol." Do you see
- 16 that?
- 17 A. Yes.
- 18 Q. Is it your testimony that you or Moderna
- 19 thought of this formulation?

20 A.

So,

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EXHIBIT 26

UNITED STATES SECURITIES AND EXCHANGE COMMISSION Washington, D.C. 20549

| FORM 8-K |
|----------|
| |

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event Reported): February 22, 2018

Arbutus Biopharma Corporation

(Exact Name of Registrant as Specified in Charter)

British Columbia, Canada (State or Other Jurisdiction of Incorporation)

001-34949 (Commission File Number)

980597776 (I.R.S. Employer Identification Number)

100-8900 Glenlyon Parkway, Burnaby, British Columbia, Canada V5J 5J8

(Address of Principal Executive Offices) (Zip Code)

(604) 419-3200

(Registrant's telephone number, including area code)

(Former name or former address, if changed since last report)

| Check the appropriate box | below if the Form 8-K filing | is intended to simultaneous | ously satisfy the filing | obligation of the re | egistrant under any | of the following |
|---------------------------|------------------------------|-----------------------------|--------------------------|----------------------|---------------------|------------------|
| provisions: | | | | | | |

| [] | Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425) |
|-----|---|
| [] | Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12) |
| [] | Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b)) |
| [] | Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c)) |
| | check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or of the Securities Exchange Act of 1934 (17 CFR §240.12b-2). Emerging growth company [] |
| | ing growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or ncial accounting standards provided pursuant to Section 13(a) of the Exchange Act. [] |
| | |
| | |

Item 8.01. Other Events. Case 1:22-cv-00252-JDW Document 535 Filed 08/01/25 Page 246 of 262 PageID #:

On February 22, 2018, Arbutus issued a press release to announce that litigation be a Acuitas Therapeutics on October 25, 2016 in the Supreme Court of British Columbia has been settled before trial. The litigation centered on Acuitas' rights to use and sublicense Arbutus pre-April 15, 2010 LNP technology under a cross license agreement dated November 12, 2012. On February 7, 2017, Arbutus obtained an injunction preventing Acuitas from further providing Arbutus LNP technology to any third party.

The settlement agreement was signed by the parties on February 21, 2018.

The settlement stipulates that the four non-exclusive viral vaccine sublicenses previously granted to Moderna are the only sublicenses to survive. These four sublicenses, previously granted by Acuitas to Moderna under the pre-April 15, 2010 Arbutus LNP patent families, are each limited to a specific viral target.

A copy of the press release is attached to this report as Exhibit 99.1 and incorporated by reference herein.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits:

99.1 Press Release issued by the Company on February 22, 2018.

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Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Arbutus Biopharma Corporation

Date: February 22, 2018 By: /s/ Koert VandenEnden

Koert VandenEnden Interim CFO

Case 1:22-cv-00252-JDW Document 535 Filed 08/01/25 Page 248 of 262 PageID #:

Arbutus Settles Litigation, Termina Acuitas' Rights to LNP Technology

Acuitas has No Further Rights to Use or Sublicense Arbutus LNP Technology Arbutus Consolidates LNP Patent Estate Enabling RNAi, mRNA, and Gene-editing Therapeutics

VANCOUVER, B.C. and WARMINSTER, Pa., Feb. 22, 2018 (GLOBE NEWSWIRE) -- Arbutus Biopharma Corporation (Nasdaq:ABUS), an industry-leading hepatitis B virus (HBV) therapeutic solutions company, today announced that litigation initiated by Acuitas Therapeutics on October 25, 2016 in the Supreme Court of British Columbia has been settled before trial. The litigation centered on Acuitas' rights to use and sublicense Arbutus pre-April 15, 2010 LNP technology under a cross license agreement dated November 12, 2012. On February 7, 2017, Arbutus obtained an injunction preventing Acuitas from further providing Arbutus LNP technology to any third party.

"This settlement terminates Acuitas' right to use or sublicense our LNP technology going forward, making permanent the effect of the Court's prior injunction," said Dr. Mark J Murray, Arbutus President and CEO. "Arbutus LNP represents the most clinically validated delivery technology suitable for RNAi, mRNA therapeutics and gene editing applications. With the settlement of the Acuitas litigation, Arbutus has now consolidated its LNP intellectual property estate. This is a major milestone which establishes Arbutus as the owner and only source of this industry-leading technology platform with the ability to develop a full range of applications."

The settlement stipulates that the four non-exclusive viral vaccine sublicenses previously granted to Moderna are the only sublicenses to survive. These four sublicenses, previously granted by Acuitas to Moderna under the pre-April 15, 2010 Arbutus LNP patent families, are each limited to a specific viral target. Moderna has no other rights to Arbutus' broad suite of LNP intellectual property.

About Arbutus Biopharma

Arbutus Biopharma Corporation is a biopharmaceutical company dedicated to discovering, developing, and commercializing a cure for patients suffering from chronic HBV infection. For more information, please visit www.arbutusbio.com.

Contact Information

Investors

Tiffany Tolmie Manager, Investor Relations Phone: 604-419-3200 Email: ttolmie@arbutusbio.com

<u>Media</u>

David Schull Russo Partners Phone: 858-717-2310

Email: david.schull@russopartnersllc.com

EXHIBIT 27

- 1 SARS-CoV-2 mRNA Vaccine Development Enabled by Prototype Pathogen Preparedness
- 3 Kizzmekia S. Corbett^{1#}, Darin Edwards^{2#}, Sarah R. Leist^{3#}, Olubukola M. Abiona¹, Seyhan
- 4 Boyoglu-Barnum¹, Rebecca A. Gillespie¹, Sunny Himansu², Alexandra Schäfer³, Cynthia T.
- 5 Ziwawo¹, Anthony T. DiPiazza¹, Kenneth H. Dinnon³, Sayda M. Elbashir², Christine A. Shaw²,
- Angela Woods², Ethan J. Fritch⁴, David R. Martinez³, Kevin W. Bock⁵, Mahnaz Minai⁵, Bianca
- 7 M. Nagata⁵, Geoffrey B. Hutchinson¹, Kapil Bahl², Dario Garcia-Dominguez², LingZhi Ma²,
- 8 Isabella Renzi², Wing-Pui Kong¹, Stephen D. Schmidt¹, Lingshu Wang¹, Yi Zhang¹, Laura J.
- 9 Stevens⁶, Emily Phung⁷, Lauren A. Chang¹, Rebecca J. Loomis¹, Nedim Emil Altaras², Elisabeth
- Narayanan², Mihir Metkar², Vlad Presnyak², Catherine Liu¹, Mark K. Louder¹, Wei Shi¹,
- 11 Kwanyee Leung¹, Eun Sung Yang¹, Ande West³, Kendra L. Gully³, Nianshuang Wang⁸, Daniel
- Wrapp⁸, Nicole A. Doria-Rose¹, Guillaume Stewart-Jones², Hamilton Bennett², Martha C.
- Nason⁹, Tracy J. Ruckwardt¹, Jason S. McLellan⁸, Mark R. Denison⁶, James D. Chappell⁶, Ian
- N. Moore⁵, Kaitlyn M. Morabito¹, John R. Mascola¹, Ralph S. Baric^{3,4}, Andrea Carfi^{2*}, Barney S.
- 15 Graham^{1*}

16

18

2

- 17 *Authors have equal contribution to this study
- 19 ¹Vaccine Research Center; National Institute of Allergy and Infectious Diseases; National
- 20 Institutes of Health; Bethesda, Maryland, 20892; United States of America
- ²Moderna Inc., Cambridge, MA, 02139; United States of America
- ³Department of Epidemiology; University of North Carolina at Chapel Hill; Chapel Hill, North
- 23 Carolina, 27599; United States of America
- ⁴Department of Microbiology and Immunology, School of Medicine, University of North Carolina
- at Chapel Hill; Chapel Hill, North Carolina, 27599; United States of America

223 **Competing Interest Declaration** 224 225 K.S.C., N.W., J.S.M., and B.S.G. are inventors on International Patent Application No. WO/2018/081318 entitled "Prefusion Coronavirus Spike Proteins and Their Use." K.S.C., O.M.A., 226 G.B.H., N.W., D.W., J.S.M. and B.S.G. are inventors on US Patent Application No. 62/972,886 227 228 entitled "2019-nCoV Vaccine". R.S.B. filed an invention report for the SARS-CoV-2 MA virus 229 (UNC ref. #18752). 230 231 **Additional Information** Correspondence and requests for materials should be addressed to Barney S. Graham, 232 bgraham@nih.gov and Andrea Carfi, andrea.carfi@modernatx.com. 233 234 Methods 235 MERS-CoV S-2P and SARS-CoV-2 S-2P mRNA synthesis and lipid nanoparticle formulation 236 237 For each vaccine, T7 RNA polymerase-mediated transcription was used in vitro to synthesize the mRNA from a linearized DNA template, which flanked the immunogen open-reading frames 238 with the 5' and 3' untranslated regions and a poly-A tail as described previously 29. mRNA was 239 then purified, diluted in citrate buffer to the desired concentration and encapsulated into lipid 240 nanoparticles (LNP) by ethanol drop nanoprecipitation. At molar ratio of 50:10:38.5:1.5 241 (ionizable lipid:DSPC:cholesterol:PEG-lipid), lipids were dissolved in ethanol and combined with 242 243 a 6.25-mM sodium acetate buffer (pH 5) containing mRNA at a ratio of 3:1 (aqueous:ethanol). Formulations were dialyzed against phosphate-buffered saline (pH 7.4) for at least 18 hr, 244 concentrated using Amicon ultracentrifugal filters (EMD Millipore), passed through a 0.22-µm 245 246 filter and stored at -20°C until use. All formulations underwent quality control for particle size,

EXHIBIT 28

SARS-CoV-2 mRNA vaccine design enabled by prototype pathogen preparedness

https://doi.org/10.1038/s41586-020-2622-0

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Published online: 5 August 2020

Check for updates

Kizzmekia S. Corbett^{1,10}, Darin K. Edwards^{2,10}, Sarah R. Leist^{3,10}, Olubukola M. Abiona¹, Seyhan Boyoglu-Barnum¹, Rebecca A. Gillespie¹, Sunny Himansu², Alexandra Schäfer³, Cynthia T. Ziwawo¹, Anthony T. DiPiazza¹, Kenneth H. Dinnon³, Sayda M. Elbashir², Christine A. Shaw², Angela Woods², Ethan J. Fritch⁴, David R. Martinez³, Kevin W. Bock⁵, Mahnaz Minai⁵, Bianca M. Nagata⁵, Geoffrey B. Hutchinson¹, Kai Wu², Carole Henry², Kapil Bahl², Dario Garcia-Dominguez², LingZhi Ma², Isabella Renzi², Wing-Pui Kong¹, Stephen D. Schmidt¹, Lingshu Wang¹, Yi Zhang¹, Emily Phung^{1,6}, Lauren A. Chang¹, Rebecca J. Loomis¹, Nedim Emil Altaras², Elisabeth Narayanan², Mihir Metkar², Vlad Presnyak², Cuiping Liu¹, Mark K. Louder¹, Wei Shi¹, Kwanyee Leung¹, Eun Sung Yang¹, Ande West³, Kendra L. Gully³, Laura J. Stevens⁷, Nianshuang Wang⁸, Daniel Wrapp⁸, Nicole A. Doria-Rose¹, Guillaume Stewart-Jones², Hamilton Bennett², Gabriela S. Alvarado¹, Martha C. Nason⁹, Tracy J. Ruckwardt¹, Jason S. McLellan⁸, Mark R. Denison⁷, James D. Chappell⁷, Ian N. Moore⁵, Kaitlyn M. Morabito¹, John R. Mascola¹, Ralph S. Baric^{3,4}, Andrea Carfi² & Barney S. Graham¹

A vaccine for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is needed to control the coronavirus disease 2019 (COVID-19) global pandemic. Structural studies have led to the development of mutations that stabilize *Betacoronavirus* spike proteins in the prefusion state, improving their expression and increasing immunogenicity¹. This principle has been applied to design mRNA-1273, an mRNA vaccine that encodes a SARS-CoV-2 spike protein that is stabilized in the prefusion conformation. Here we show that mRNA-1273 induces potent neutralizing antibody responses to both wild-type (D614) and D614G mutant² SARS-CoV-2 as well as CD8⁺ T cell responses, and protects against SARS-CoV-2 infection in the lungs and noses of mice without evidence of immunopathology. mRNA-1273 is currently in a phase III trial to evaluate its efficacy.

Since its emergence in December 2019, SARS-CoV-2 has accounted for more than 30 million cases of coronavirus disease 2019 (COVID-19) worldwide in 9 months³. SARS-CoV-2 is the third novel Betacoronavirus in the past 20 years to cause substantial human disease; however, unlike its predecessors SARS-CoV and Middle East respiratory syndrome coronavirus (MERS-CoV), SARS-CoV-2 is transmitted efficiently from person to person. In the absence of a vaccine, public health measures such as quarantine of newly diagnosed cases, contact tracing, use of face masks and physical distancing have been put into place to reduce transmission⁴. It is estimated that until 60-70% of the population have immunity, COVID-19 is unlikely to be sufficiently well-controlled for normal human activities to resume. If immunity remains solely dependent on infection, even at a case fatality rate of 1%, more than 40 million people could succumb to COVID-19 globally⁵. Therefore, rapid development of vaccines against SARS-CoV-2 will be critical for changing the global dynamics of this virus.

The spike (S) protein, a class I fusion glycoprotein analogous to influenza haemagglutinin, respiratory syncytial virus (RSV) fusion glycoprotein (F) and human immunodeficiency virus gp160 (Env),

is the major surface protein on the coronavirus virion and the primary target for neutralizing antibodies. S proteins undergo marked structural rearrangement to fuse virus and host cell membranes, enabling delivery of the viral genome into target cells. We previously showed that prefusion-stabilized protein immunogens that preserve neutralization-sensitive epitopes are an effective vaccine strategy for enveloped viruses such as RSV^{6-10} . Subsequently, we identified 2 proline substitutions (2P) at the apex of the central helix and heptad repeat 1 that effectively stabilized MERS-CoV, SARS-CoV and human coronavirus HKU1S proteins in the prefusion conformation 1,11,12. Similar to other prefusion-stabilized fusion proteins, MERS-CoVS(2P) protein was more immunogenic at lower doses than wild-type S protein¹. The 2P mutation has similar effects on the stability of S proteins from other betacoronaviruses, suggesting a generalizable approach for designing stabilized-prefusion Betacoronavirus S protein antigens for vaccination. Such generalizability is fundamental to the prototype pathogen approach for pandemic preparedness^{13,14}.

Coronaviruses have long been predicted to have a high probability of causing zoonotic disease and pandemics^{15,16}. As part of our pandemic

Vaccine Research Center, National Institute of Allergy and Infectious Diseases, National Institutes of Health, Bethesda, MD, USA. ²Moderna Inc, Cambridge, MA, USA. ³Department of Epidemiology, Gillings School of Global Public Health, University of North Carolina at Chapel Hill, NC, USA. ⁴Department of Microbiology and Immunology, School of Medicine, University of North Carolina at Chapel Hill, NC, USA. ⁵National Institute of Allergy and Infectious Diseases, National Institutes of Health, Bethesda, MD, USA. ⁶Institute for Biomedical Sciences, George Washington University, Washington, DC, USA. ⁷Department of Pediatrics, Vanderbilt University Medical Center, Nashville, TN, USA. ⁸Department of Molecular Biosciences, University of Texas at Austin, Austin, TX, USA. ⁸Biostatistics Research Branch, Division of Clinical Research, National Institute of Allergy and Infectious Diseases, National Institutes of Health, Bethesda, MD, USA. ¹⁰These authors contributed equally: Kizzmekia S. Corbett, Darin K. Edwards, Sarah R. Leist. ¹⁰E-mail: andrea.carfi@modernatx.com; bgraham@nih.gov

Article

Methods

Data reporting

No statistical methods were used to predetermine sample size. The experiments were not randomized. The investigators were not blinded to allocation during experiments and outcome assessment.

Pre-clinical mRNA-1273 mRNA and LNP production process

A sequence-optimized mRNA encoding SARS-CoV-2 S(2P) protein was synthesized in vitro using an optimized T7 RNA polymerase-mediated transcription reaction with complete replacement of uridine by N1-methyl-pseudouridine 34 . The reaction included a DNA template containing the immunogen open reading frame flanked by 5^\prime untranslated region (UTR) and 3^\prime UTR sequences and was terminated by an encoded polyA tail. After transcription, the Cap1 structure was added to the 5^\prime end using vaccinia capping enzyme (New England Biolabs) and Vaccinia 2^\prime O-methyltransferase (New England Biolabs). The mRNA was purified by oligo-dT affinity purification, buffer exchanged by tangential flow filtration into sodium acetate, pH 5.0, sterile filtered, and kept frozen at $-20\,^{\circ}\text{C}$ until further use.

The mRNA was encapsulated in a lipid nanoparticle through a modified ethanol-drop nanoprecipitation process as described previously 20 . In brief, ionizable, structural, helper and polyethylene glycol lipids were mixed with mRNA in acetate buffer, pH 5.0, at a ratio of 2.5:1 (lipids:mRNA). The mixture was neutralized with Tris-Cl pH 7.5, sucrose was added as a cryoprotectant, and the final solution was sterile filtered. Vials were filled with formulated LNP and stored frozen at $-70\,^{\circ}\mathrm{C}$ until further use. The drug product underwent analytical characterization, which included the determination of particle size and polydispersity, encapsulation, mRNA purity, double stranded RNA content, osmolality, pH, endotoxin and bioburden, and the material was deemed acceptable for in vivo study.

MERS-CoV and SARS-CoV protein expression and purification

Vectors encoding MERS-CoVS- $2P^{1}$ and SARS-CoVS- $2P^{23}$ were generated as previously described with the following small amendments. Proteins were expressed by transfection of plasmids into Expi293 cells using Expifectamine transfection reagent (ThermoFisher) in suspension at 37 °C for 4–5 days. Transfected cell culture supernatants were collected, buffer exchanged into $1\times$ PBS, and protein was purified using Strep-Tactin resin (IBA). For proteins used for mouse inoculations, tags were cleaved with addition of HRV3C protease (ThermoFisher) (1% wt/wt) overnight at 4 °C. Size-exclusion chromatography using Superose 6 Increase column (GE Healthcare) yielded final purified protein.

$Design and production of recombinant minifibritin foldon \\ protein$

A mammalian codon-optimized plasmid encoding foldon inserted minifibritin (ADIVLNDLPFVDGPPAEGQSRISWIKNGEEILGADTQYGSE GSMNRPTVSVLRNVEVLDKNIGILKTSLETANSDIKTIQEAGYIPEAPRDGQA YVRKDGEWVLLSTFLSPALVPRGSHHHHHHSAWSHPQFEK) with a C-terminal thrombin cleavage site, $6\times$ His tag, and Strep-Tagll was synthesized and subcloned into a mammalian expression vector derived from pLEXm. The construct was expressed by transient transfection of Expi293 (ThermoFisher) cells in expression at $37\,^{\circ}\text{C}$ for 5 days. The protein was first purified with a Ni $^{2+}$ -nitrilotriacetic acid resin (GE Healthcare) using an elution buffer consisting of $50\,\text{mM}$ Tris-HCl, pH $7.5,400\,\text{mM}$ NaCl and $300\,\text{mM}$ imidazole pH 8.0, followed by purification with StrepTactin resin (IBA) according to the manufacturer's instructions.

Cell lines

HEK293T/17 (ATCC CRL-11268), Vero E6 (ATCC), Huh7.5 cells (provided by D. R. Taylor, US Food and Drug Administration) and ACE2-expressing 293T cells (provided by M. Farzan, Scripps Research Institute) were cultured in Dulbecco's modified Eagle's medium (DMEM) supplemented to the provided by M. Farzan, Scripps Research Institute) were cultured in Dulbecco's modified Eagle's medium (DMEM) supplemented to the provided by M. Farzan, Scripps Research Institute) were cultured in Dulbecco's modified Eagle's medium (DMEM) supplemented to the provided by M. Farzan, Scripps Research Institute) were cultured in Dulbecco's modified Eagle's medium (DMEM) supplemented to the provided by M. Farzan, Scripps Research Institute) were cultured in Dulbecco's modified Eagle's medium (DMEM) supplemented to the provided by M. Farzan, Scripps Research Institute) were cultured in Dulbecco's modified Eagle's medium (DMEM) supplemented to the provided by M. Farzan, Scripps Research Institute) were cultured in Dulbecco's modified Eagle's medium (DMEM) supplemented to the provided by M. Farzan, Scripps Research Institute) were cultured in Dulbecco's modified Eagle's medium (DMEM) supplemented to the provided by M. Farzan (DMEM) supplemented by M. Farzan (DMEM) suppl

with 10% FBS, 2 mM glutamine and 1% penicillin–streptomycin at 37 °C and 5% CO2. Vero E6 cells used in plaque assays to determine lung and nasal turbinate viral titres were cultured in DMEM supplemented with 10% Fetal Clone II and 1% antibiotic–antimycotic at 37 °C and 5% CO2. Vero E6 cells used in plaque-reduction neutralization test (PRNT) assays were cultured in DMEM supplemented with 10% Fetal Clone II and amphotericin B (0.25 μg ml $^{-1}$) at 37 °C and 5% CO2. Lentivirus encoding hACE2-P2A-TMPRSS2 was made to generate A549-hACE2-TMPRSS2 cells, which were maintained in DMEM supplemented with 10% FBS and 1 μg ml $^{-1}$ puromycin. Expi293 cells were maintained in the manufacturer's suggested medium. BHK-21/WI-2 cells were obtained from Kerafast and cultured in DMEM with 5% FBS at 37 °C and 6–8% CO2. Cell lines were not authenticated. All cells lines were tested for mycoplasma and remained negative.

In vitro mRNA expression

HEK293T cells were transiently transfected with mRNA encoding SARS-CoV-2 wild-type S or S(2P) protein using a TranlT mRNA transfection kit (Mirus). After 24 h, the cells were collected and resuspended in fluorescence-activated cell sorting (FACS) buffer (1× PBS, 3% FBS, 0.05% sodium azide). To detect surface-protein expression, the cells were stained with $10\,\mu g\,ml^{-1}\,ACE2$ –Flag (Sigma) or $10\,\mu g\,ml^{-1}\,CR3022^{35}$ in FACS buffer for 30 min on ice. Thereafter, cells were washed twice in FACS buffer and incubated with FITC–anti-Flag (Sigma) or Alexa Fluor 647–goat anti-human lgG (Southern Biotech) in FACS buffer for 30 min on ice. Live/Dead aqua fixable stain (Invitrogen) were used to assess viability. Data acquisition was performed on a BD LSRII Fortessa instrument (BD Biosciences) and analysed by FlowJo software v.10 (Tree Star).

Mouse models

Animal experiments were carried out in compliance with all pertinent US National Institutes of Health regulations and approval from the Animal Care and Use Committee (ACUC) of the Vaccine Research Center, Moderna Inc., or University of North Carolina at Chapel Hill. For immunogenicity studies, 6- to 8-week-old female BALB/c (Charles River), BALB/cJ, C57BL/6J or B6C3F1/J mice (Jackson Laboratory) were used. mRNA formulations were diluted in 50 µl 1× PBS, and mice were inoculated intramuscularly in the same hind leg for both prime and boost. Control mice received PBS because previous studies have demonstrated the mRNA formulations being tested do not create substantial levels of nonspecific immunity beyond a few days^{36–38}. For all SARS-CoV-2 S(2P) protein vaccinations, mice were inoculated intramuscularly with SAS as previously described¹. For S(2P) + alum immunizations, SARS-CoV-2S(2P) protein + 250 µg alum hydrogel was delivered intramuscularly. For challenge studies to evaluate MERS-CoV vaccines, 16- to 20-week-old male and female 288/330^{+/+}mice²² were immunized. Four weeks post-boost, pre-challenge sera were collected from a subset of mice, and the remaining mice were challenged with 5 × 10⁵ PFU of a mouse-adapted MERS-CoV EMC derivative, m35c4³⁹. On day 3 post-challenge, lungs were collected and haemorrhage and viral titre were assessed according to previously published methods⁴⁰. For challenge studies to evaluate SARS-CoV-2 vaccines, BALB/cJ mice were challenged with 105 PFU SARS-CoV-2 MA. This virus contains two mutations (Q498T/P499Y) in the receptor binding domain that enable binding of SARS-CoV-2S protein to the mouse ACE2 receptor and infection and replication in the upper and lower respiratory tract³². On day 2 post-challenge, lungs and nasal turbinates were collected for viral titre assessment according to previously published methods³². Sample size for animal experiments was determined on the basis of criteria set by institutional ACUC. Experiments were not randomized or blinded.

Histology

Lungs were collected from mice at the indicated study end points and placed in 10% neutral-buffered formalin until adequately fixed. Thereafter, tissues were trimmed to a thickness of 3-5 mm, processed and paraffin

EXHIBIT 29

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Moderna Therapeutics, Inc.

Petitioner

v.

Protiva Biotherapeutics, Inc.

Patent Owner

Case No. IPR2018-00739 U.S. Patent No. 9,364,435

PETITIONER'S REPLY TO PATENT OWNER RESPONSE

Mail Stop: PATENT BOARD
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amounts of PEG to be efficacious. See EX2009, 22-31. But Dr. Thompson is not qualified to offer those opinions. Dr. Thompson does not appear to have any significant experience with lipid particle formation and use in the context of delivering therapeutic payloads. He researches carrier molecules using polymers, not lipids. EX1019, 21:9-25 ("...we make stabilized nucleic acid particles, but they're not lipid particles. We make them out of polymers."). His experience with SNALPs is limited to using them as benchmarks in his research. Id., 46:3-10, 49:11-17. He admitted that he has not worked with ionizable cationic lipids, like DLinDMA, used in the testing of the '069 and '127 patents. Id., 74:20-75:13. Finally, Dr. Thompson testified that he did not even completely review references provided to him by Patent Owner's counsel that he cited in his declarations. EX1020, 388:9-13, 389:17-22 ("...I did not read through the entire document..."), 397:24-398:11. For these reasons, Dr. Thompson's opinions should be accorded little if any weight.

IV. CLAIM CONSTRUCTION

Petitioner and its expert submit that the Board's construction of "nucleic acidlipid particle" is appropriate and agree therewith. EX1021 ("Janoff"), ¶13.

In an effort to avoid the prior art, Patent Owner seeks to import limitations into the claims that the claimed particles are "SNALPs," "serum stable," and limited to "systemic use." Resp. 10-13 (challenging Board's construction as "unreasonably broad in view of the specification").

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Regarding SNALPs, the Board correctly noted that Patent Owner's claim construction position, with these added limitations, is "inconsistent with claim 1 because it limits the term 'nucleic acid-lipid particle' as used in claim 1 to the definition of a stable nucleic acid-lipid particle or SNALP." Paper 15, 9. The '435 patent states repeatedly that SNALPs are mere examples of nucleic acid-lipid particles of the invention. E.g., EX1001, 11:46 ("...lipid particles of the invention (e.g., SNALP)"). While Patent Owner claims that Dr. Janoff equated the two terms (Resp., 10), he was merely noting that the carrier particles described in the '127 specification were SNALPs. See, e.g., EX2028, 119:5-22 ("Q. So from your perspective, the '127 patent is defining a lipid particle as a SNALP?...A. No, I didn't say that..."). Regarding the construction of the term "nucleic acid-lipid particles" in the claims, he pointed to the portion of the disclosure relating to the definition of "lipid particle." *Id.*, 200:4-201:9.

Along similar lines, Patent Owner and its expert argue that the claimed particles should be limited to those that are serum stable to allow for systemic use *in vivo*. Resp., 2 (high cationic lipid and low PEG not expected to be effective *in vivo*), 17 ('196 PCT may be limited to 5-15% for systemic use), 43 ("...the inventive lipid particles are serum-stable nucleic acid-lipid particles that are 'extremely useful for

¹ Because the '127 and '435 have substantial overlap in their disclosures, Patent Owner references this testimony as applying to both patents. *See* Resp., 12.

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systemic applications...."); EX1019, 93:12-94:13 (reading serum stability into claims for analysis), 91:19-92:5 (reading therapeutic function into claims); 117:11-118:20 ("Unless your goal is something else that doesn't require in vivo efficacy...."), EX1020, 215:17-25 (same). As the Board previously noted, the claims and the specification are "not limited to *in vivo* use." Paper 15, 10; EX1001, 6:31-34 ("...both in vitro and in vivo...."). Patent Owner also argues that all nucleic acid in the '435 particles is protected "from enzymatic degradation" and, thus, necessarily serum stable. Resp., 12. Patent Owner's expert, however, testified that "[i]f there are lamellar phases there, there's a good chance that the nucleic acid is exposed, it's not been properly encapsulated." EX1019, 126:4-11. The Board should thus once again reject Patent Owner's attempt to interject additional limitations into the claims.

V. THE INSTITUTED GROUNDS

Based upon the evidence presented, Petitioner has demonstrated that claims 1-20 of the '435 patent are invalid by a preponderance of the evidence. Janoff, ¶14. Each of the cited prior art references disclose particles formulated with overlapping ranges for each of the lipid components identified in the '435 patent. EX1002-1004. In addition, the '554 publication created an anticipatory particle with lipid components meeting each of the claim limitations in claim 1. EX1004, Table IV (L054 formulation).

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EX2028, 41:9-42:2 ("A. I'd like you to point me to where that is in my declaration so that I can see it in context. Q. That's not responsive to the question, Dr. Janoff."); 43:7-44:20 (refusing reference to patents); 45:5-46:25 (same); 48:5-12 (same); 49:18-50:5 (same).

Dr. Janoff, nonetheless, provided answers to the extent possible. *Id.*, 58:1-59:1 (defining liposome); 65:18-23 (same); 193:5-25 (defining "lipid particle" in context of '069 patent); 198:23-199:18 (defining "encapsulation" in context of '127 patent).

Patent Owner also argues that Dr. Janoff's unfamiliarity with a patent from 20 years ago on which he is listed as an inventor is somehow is evasive. Resp., 7-8. Dr. Janoff merely requested the opportunity to review the reference.

Dated: March 22, 2019

Respectfully submitted,

By: /s/ Michael R. Fleming

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